THE EFFECTIVENESS OF COMMERCIAL WEIGHT LOSS PROGRAMMES: A SYSTEMATIC REVIEW AND EVALUATION OF A PHARMACIST-LED WEIGHT MANAGEMENT CLINIC

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Abstract

Commercial weight loss programmes (CWLPs) are structured weight loss programmes, which are provided to the public by commercial organisations for profit. These programmes offer a weight management service for overweight or obese adults who are willing and able to pay for their participation. There are few studies that have shown CWLPs are more effective than either usual or standard care in various healthcare settings. The extent to which elements of CWLPs contribute to weight reduction is not clear from these studies.

The studies presented in this thesis aimed to i) systematically review the effectiveness of CWLPs in randomised controlled trials and ii) to evaluate the effectiveness of a pharmacist-led weight management clinic, Boots Pharmacy Weight Loss Programme (BPWLP), in achieving meaningful weight loss of the initial body weight at three months in overweight and obese clients who received a combination of orlistat, and diet and exercise advice.

The systematic review evaluated percentage weight loss or change and used a narrative synthesis. Nine electronic databases (1980-2011) were searched. The review studies published in English were included and their quality was assessed, including assessment of risk of bias. The number of total titles, abstracts and full articles reviewed were 8484, 772 and 153, respectively. The final number of papers included in the review was 20 randomised studies of CWLPs, which were selected based on the application of inclusion and exclusion criteria.

The evaluation of the BPWLP involved analysis of data from randomly collected customer record forms (CRFs) for clients who participated in the programme from January 2006 to January 2009. Five hundred and fifty-seven records were collected from 10 Boots pharmacies. Demographics data, history information, biometric data and information about the supply of orlistat were collected. Change in body weight (kg) was compared at baseline and three months using Wilcoxon Signed Rank Test.

Seventy percent of the studies included in the systematic review were conducted in the US. There were three potential elements of effective CWLPs, which were calorie restriction, exercise and support. At 12 weeks, mean weight loss ranged from 3.3 to 12.7 kg.

The mean weight loss in the BPWLP was 5.8 kg ($p < 0.001$). Similarly, sensitivity analysis using last-observation-carried-forward (LOCF) showed a statistically significant weight loss ($p < 0.001$) associated with the BPWLP. Sixty-two percent of clients, who completed the BPWLP, lost at least 5% of their initial body weight at three months. Although the BPWLP had a high dropout rate (70%), clients mainly left the programme because they achieved their desired weight loss.

The studies presented in this thesis have shown that CWLPs are effective in helping clients to lose weight. The systematic review shows that the combination of calorie restriction, structured exercise and support is an effective first-line strategy in obesity treatment. The BPWLP, which uses orlistat 120 mg in combination with advice and support on diet and exercise, was shown to be effective in achieving weight loss for clients and is considered a second-line treatment. Health care professionals and policy makers should acknowledge and adopt such strategies in order to tackle the problem of obesity. In particular, pharmacists have an important role to play in facilitating effective weight reduction through the provision of dietary and exercise advice and the prescribing of orlistat. Further study should focus on the factors which contribute to long-term weight maintenance and the cost-effectiveness of CWLPs.

Published abstracts

Sriwisit S, Boardman H, Avery A. Retrospective evaluation of pharmacist-led weight management clinics: a feasibilty study. *International Journal of Pharmacy Practice* 2011;19(Suppl 1):25-26.

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List of Abbreviations and Acronyms

ASP	Authorised sign-off person
BG	Blood glucose
BMI	Body Mass Index
BP	Blood pressure
BPWLP	Boots Pharmacy Weight Loss Programme
BW	Body weight
CHD	Coronary Heart Disease
CI	Confidence Interval
CONSORT	Consolidated Standards of Reporting Trials
COPD	Chronic Obstructive Pulmonary Disease
CRF(s)	Customer Record Form(s)
CWLP(s)	Commercial Weight Loss Programme(s)
DBP	Diastolic blood pressure
DM	Diabetes Mellitus
EU	European
GI	gastrointestinal
GORD	Gastro-Oesophageal Reflux disease
GP	General Practitioner
GSK	GlaxoSmithKline
HBP	High blood pressure
HDL	High-density lipoprotein cholesterol
HMR	Health Management Resources
IMA	Independent medical agency
ITT	Intention-to-treat
JC	Jenny Craig

kcal	kilocalorie
kg	kilogram
lbs	pounds
LCD	Low-calorie diet
LDL	Low density lipoprotein cholesterol
LEARN	Lifestyle, Exercise, Attitudes, Relationships and Nutrition
LL	LighterLife
LOCF	Last observation carried forward
m^2	metre square
Md	Median
MeSH	Medical Subject Heading
MR(s)	Meal replacement(s)
N, n	number
NCWLPs	Non-Commercial Weight Loss Programme(s)
NHS	National Health Service
NICE	National Institute for Health and Clinical Excellence
OTC	Over-the-counter
P	Pharmacy medicine
p(-value)	Probability (value)
PCT	Primary Care Trust
PGDs	Patient Group Directions
POM	Prescription only medicine
RC	Rosemary Conley
RCT	Randomized controlled trial
RPM	The regional pharmacy manager
RPSGB	The Royal Pharmaceutical Society of Great Britain

SBP	Systolic blood pressure
SD	Standard Deviation
SE	Standard Error
SPC	Summary of product characteristics
st	stone
SW	Sliming World
UK	The United Kingdom
US	The United States
VLCD	Very low-calorie diets
vs	versus
WC	Waist Circumference
WHO	World Health Organization
WW	Weight Watchers

Chapter 1

Introduction and background

This first chapter provides the background and rationale for the study and structure of the thesis. It also presents a review of the literature relevant to this research. The main topic areas covered are: health care systems in the UK, overview of obesity, principles of prevention and treatment of obesity, anti-obesity medicine, pharmacist-led weight management clinics, pharmacist interventions, the role of the pharmacist in obesity management and pharmacy practice in the UK. Finally the aim and objectives of the study are described.

1.1 Introduction

Since the mid-1980s, obesity has become an important problem of global concern as there is a worldwide obesity epidemic with its resulting public health problems.[1] The World Health Organisation (WHO) predicts that obesity affects approximately 400 million adults worldwide and by 2015 will affect 700 million adults.[2, 3] In the United States (US), the prevalence of being overweight or obese increased from 12.8% to 22.5% between 1960 and 1994. The rise in obesity in the US is continuing; in 2005, 31% of adults were obese.[4, 5] Similarly in European countries, the prevalence of obesity has continually increased in both adults and children. In the United Kingdom (UK) obesity, which is one of the most common health problems, has tripled since 1980 and also has the highest prevalence amongst European countries. In 2003 and 2004, around 15% of men and 18% of women in England were obese.[6-8] By 2007

almost one quarter (24%) of both were obese.[9] However, the latest estimates predict obesity will double by 2050 when half the population will be obese.

With such high levels of obesity in the UK many studies have advocated rigorous weight-loss interventions such as nutrition counselling, physical activity, behavioural modification and social support.[10, 11] These interventions may be able to achieve and maintain weight loss in some individuals but they have not been widely implemented. Other studies suggest that pharmacological treatment can be an effective adjunct to dietary and lifestyle interventions in the treatment of obesity.[12-14]

The first-line strategy in obesity guidelines recommends that people maintain a healthy weight by balancing 'calories in' and 'calories out' and eating a healthy diet. This strategy is to improve people's general health and reduce the risk of developing diseases related to obesity.[15] Other strategies to help people achieve and maintain a healthy weight include increasing physical activity levels, lifestyle or behavioural interventions which should be undertaken for at least three months for the effects to be seen. Where people are struggling to lose weight with lifestyle modification, then pharmacological treatment should be considered. Pharmacotherapy, alongside a restricted calorie diet and increased exercise, is a second line treatment. However, there are several options available to reduce weight including reduced-energy diets, physical activity, behaviour modification and surgery.[16]

In the UK there are many providers of weight loss programmes. Such programmes can be either accessed through National Health Service (NHS) or commercial sources. Commercial weight loss programmes (CWLPs) provide an opportunity for

support in losing weight for patients who are prepared to pay to participate. Although the CWLPs are effective in achieving weight loss for overweight or obese people, it was essential to ascertain for health care providers whether or not CWLPs are more effective in weight reduction than either usual or standard care.[17] The extent to which CWLPs could contribute to reducing the obesity epidemic is unclear.

Community pharmacy is an ideal venue for weight management interventions. However, there is insufficient evidence as to the effectiveness of community pharmacy-based weight management interventions.[18] To support effective weight loss in a community pharmacy, Boots Pharmacy Weight Loss Programme (BPWLP) was designed to support overweight or obese clients in losing weight. This CWLP involves the pharmacist providing the service which combines the supply of orlistat 120 mg with advice and support about diet and physical activity.

This thesis focuses on CWLP. CWLPs are defined as structured weight loss programmes initiated by organisations delivering the intervention for profit, and include where this is in the form of the provision of vouchers or partial subsidies. This study excluded non-commercial weight loss programmes (NCWLPs), which are defined as weight loss interventions offered free of charge to the user for both short- and long-term approaches, supported by government organisations, private health care provided as a part of health insurance, from charities or social enterprises.

This thesis aims to investigate the effectiveness of CWLPs, using a systematic review and evaluation of a pharmacist-led weight management service in the UK.

1.2 Structure of the thesis

There are the five further chapters in this thesis which are described below.

Chapter two reports a systematic review of CWLPs. This study aims to assess the effectiveness of CWLPs in helping overweight and obese adults to lose weight.

Chapter three describes a pilot study to evaluate a community pharmacy CWLP. The pilot study was conducted to test the data collection method and database, together with assessing the quality of the data held in pharmacies and to provide estimates for the sample size calculation for the main study. The amendments to the study method for the main study are then discussed.

Chapter four describes a retrospective evaluation of a pharmacist-led weight management clinic. The aims of this phase of the study are to evaluate the effectiveness of a pharmacist-led weight management clinic in achieving weight loss for obese clients through a combination of orlistat supply, diet, exercise and advice.

Chapter five presents the development and testing of a questionnaire to evaluate clients' views of the Boots Pharmacy Weight Loss Programme (BPWLP).

Chapter six, the discussion, draws together the findings and discussion from the two studies. Then the practical implications for health care professionals and policy, together with the strengths and limitations of the study, are discussed. Recommendations for further research in both providing evidence for CWLPs and improving them are presented.

1.3 Background

1.3.1 Health care systems in England

The NHS was the first state organization in the world to provide free universal healthcare. In the UK, health care is mainly provided by NHS free of charge at the point of service for patients, being funded from general taxation.[19] Although health care in the UK is primarily provided by the NHS, private health care and a variety of alternative treatments are available for people who are willing and able to pay for them.

1.3.1.1 Public health care

Public health care provided by the NHS includes family doctors, specialists, dentists, pharmacists, opticians and the ambulance service. Services related to sight tests, dental treatment, prescriptions and many aspects of personal care are not free.[19] The NHS provides for anyone who is resident in the UK including EU nationals, students (on courses longer than 6 months) and anyone with a British work permit.

1.3.1.2 Private health care

Private health care in the UK aims to help people make the right choice for any treatment. It is funded by private insurance and is used by less than 8% of the UK population. Where private health care is used, it is generally to top up NHS services. Recently, some of the unused private sector capacity has been used to increase NHS capacity.[20] The involvement of the private health care sector remains comparatively small: 1.6% of Gross Domestic Product (GDP) in 2010[21] compared with the public

health care sector. Obesity treatment and weight management programmes are provided by both the private and public health care sectors.[20]

1.3.2 An overview of obesity

1.3.2.1 Definition and classification of obesity

The worldwide obesity epidemic is an important problem of global concern.[22, 23] Obesity is defined using the body measurements, body mass index (BMI) and waist circumference (WC).[22, 24] BMI is used to predict fat mass in the body which is calculated by dividing weight in kilogram (kg) by the square of height in metres (m^2). The interpretation of BMI levels for adults, aged 18 years and over, is that a BMI of 30 kg/m^2 or more defined as obesity – see Table 1.1.

Table 1.1 Classification of overweight and obesity based on BMI

Weight category	BMI (kg/m^2)	Obesity class
Underweight	<18.5	-
Normal	18.5 to 24.9	-
Overweight	25.0 to 29.9	-
Obese	30.0 to 34.9	Class I
Obese	35.0 to 39.9	Class II
Extreme Obesity	≥40	Class III

Source: Bjorntorp P. Definition and classification of obesity. *Eating Disorders and Obesity, in C.G. Fairburn and K.D. Brownell (eds.)*. New York: The Guildford Press, 2002.[23]

Measuring waist circumference (WC) is commonly used in adults as a measure of central adiposity as BMI cannot differentiate body fat mass and muscular physique. A WC greater than 102 cm for men and 88 cm for women is defined as overweight

or obese. A raised BMI, together with a high WC, indicates an increased impact of being overweight or obese on health and therefore a heightened risk of co-morbidities.[23, 24] Table 1.2 shows BMI and WC with the level of associated risk.

Table 1.2 Relationship between measurements of obesity and level of associated risk for type 2 diabetes mellitus, hypertension and cardiovascular disease

Item	BMI (kg/m^2)	Disease Risk Relative to Normal Weight and Waist Circumference	
		Men ≤102 cm (≤40 inches), Women ≤88 cm (≤35 inches)	Men >102 cm (>40 inches), Women >88 cm (>35 inches)
Underweight	<18.5	-	-
Normal	18.5 to 24.9	-	-
Overweight	25.0 to 29.9	Increased	High
Obesity I	30.0 to 34.9	High	Very high
Obesity II	35.0 to 39.9	Very high	Very high
Obesity III	≥40	Extremely high	Extremely high

Source: ASHP therapeutic position statement on the safe use of pharmacotherapy for obesity management in adults.[24]

Obesity is also a risk factor for a number of conditions that result in increasing mortality. The BMI standards were developed using Western populations and these are the standards accepted in most obesity guidelines, including those of the WHO.

The evidence from non-Western populations suggest that the standard applied should vary. The Japan Society for the Study of Obesity (JASSO) classifies BMI ≥ 25 kg/m^2 as obese and China uses a BMI of greater than 28 kg/m^2 to classify adults as obese.[25] Waist measurement standards are also different in some populations; in China a WC of over 85 cm in men and 80 cm in women conveys added risk of a raised BMI. A study by Woo et al.[26] found that WC was a useful measure in predicting mortality

and cardiovascular risk in elderly people. Similarly Janssen et al.[27] suggests waist measurement can explain the health risks; nevertheless BMI remains a significant predictor of the obesity-related health risks.[28]

1.3.2.2 Causes and risks

Causes of obesity can be divided into two main areas:[29-31]

- At an individual level a combination of both environmental and genetic causes leads to obesity. Environmental causes include increasingly sedentary lifestyles, lack of physical activity, family influence and overconsumption of energy. Overconsumption may be due to eating too many calories, high fat intake, low energy expenditure compared with calories consumed and also socio-economic factors[32-34] such as low family income, low education levels and married. Genetic causes, which influence obesity arise from processes in the body, such as reduced metabolic rate and raised blood glucose metabolism.
- At societal level increasing rates of obesity are due to an easily accessible diet and the increased reliance on cars.

Within both of these areas, contributors to the increase in obesity levels have been identified as insufficient sleep, decreased rates of smoking (due to the effect of smoking in suppressing appetite) and increased use of medication.[29, 31] The co-morbidities that increase morbidity and mortality in obese people are heart disease, type 2 diabetes, stroke and sleep apnoea – see Table 1.3. People who have three or more co-morbidities will raise morbidity and mortality.[29]

Table 1.3 Co-morbidities associated with obesity

Main co-morbidities	Other co-morbidities
Coronary Heart Disease	High blood pressure
Type 2 diabetes mellitus	Dyslipidemia: LDL* > 160 mg per dL/4.14 mmol per L, HDL** < 35 mg per dL/0.91 mmol per L
Stroke	Hypercholesterolemia
Sleep apnoea	Gastrointestinal cancers
	Osteoarthritis
	Respiratory diseases

*LDL = low-density lipoprotein cholesterol, **HDL = high- density lipoprotein cholesterol

Source: Berke EM, Morden NE. Medical Management of Obesity.[29]

1.3.3 The obesity epidemic

The WHO predicts that obesity affects approximately 400 million adults worldwide and by 2015 will affect 700 million adults.[3] It is an increasingly important issue in both developed and developing countries.

1.3.3.1 A worldwide problem

In the US, the prevalence of being overweight or obese increased from 12.8% to 22.5% between 1960 and 1994.[4] The increased prevalence of obesity is seen in both men and women.[35] The rise in obesity levels in the US is continuing: in 2005, 31% of adults were obese[5] Similarly in European countries, obesity has increased since the mid-1980s – see Table 1.4.

Table 1.4 Studies measuring the prevalence of obesity in both developed and developing countries

Study (Year, Country)	Method	Sample	Number of participants	Age (years)	The prevalence of obesity (%)		
					Men	Women	Total
North America							
Ogden, et al (2006, US)[35]	NHANES Measured	Multistage sample	4,431 in 1999-2000	20+	27.5	33.4	30.5
			2003-2004	20+	33.9	40.1	37.0
Mokdad, et al (2003, US)[36]	Cross-sectional survey: Self-reported	Random digit telephone sample	195,005	18+	21.0	20.8	20.9
Flegal, et al (1998, US)[4]	National survey: Measured, self-reported in 1988-1994	The complex, stratified and multistage probability cluster sampling	1960-1962	20-74	10.4	15.0	12.8
			1971-1974	20-74	11.8	16.2	15.2
			1976-1980	20-74	12.3	16.5	14.5
			1988-1994	20-74	20.0	24.9	22.5
Bélanger-Ducharme, F. & Tremblay, A. (2005, Canada)[37]	Cross-sectional survey: Self-reported and measured weight and height	Systematic sampling	1970-1972	20-69	8.0	13.0	10.5
			1988-1992	20-69	13.0	15.0	14.0
			2003	18+	15.9	13.9	14.9
Europe							
Gallus, et al (2006, Italy)[38]	Interview survey: Self-reported	Multistage stratified sampling	1993-1994	15+	-	-	7.0
			2,932 in 2004	18+	7.4	8.9	8.2
Carmo, et al (2006, Portugal)[39]	Cross-sectional survey: Self-reported	Systematic sampling	4,328 in 1995-1998	18-64	12.9	15.4	14.1
			6,411 in 2003-2005	18-64	14.6	13.3	13.8
Milewicz, et al (2005, Poland)[40]	Observational study: No details of BMI measurement	-	1993	20-40	6.3	8.9	7.6
			2003	20-40	6.5	15.0	10.7
			1993	40-60	15.7	22.5	19.1
			2003	40-60	23.6	36.1	29.8
Martínez, et al (2004, Spain)[41]	Cross-sectional survey: Self-reported	Systematic sampling	9,885 in 1990-2000	25-60	13.4	15.7	14.5

Note: - = Data unavailable

Table 1.4 (continued)

Study (Year, Country)	Method	Sample	Number of participants	Age (years)	The prevalence of obesity (%)		
					Men	Women	Total
Europe							
Neovius, et al (2004, Sweden)[42]	The Survey of Living Conditions: Self-reported weight and height	Random sample	12,000-15,000 in 1988/1989	16-84	5.2	5.6	5.4
			1996/1997	16-84	6.8	7.2	7.0
			2002/2003	16-84	10.6	9.9	10.3
Helmert, U. & Strube, H. (2004, Germany)[43]	Cross-sectional survey: No details of BMI measurement	-	26,614 in 1985-1998	25-69	16.2	16.2	16.2
			2002-2003	25-69	22.5	23.5	23.0
Visscher, et al (2002, Netherlands)[44]	Longitudinal survey: Measured	Systematic sampling	17,008 in 1976-1980	37-43	4.9	6.2	5.6
			7,510 in 1987-1991	37-43	7.4	7.6	7.5
			4,623 in 1993-1997	37-43	8.5	9.3	8.9
			29,141 in 1993-1997	20-59	8.5	9.6	9.1
Lahti-Koski, et al (2000, Finland)[45]	Cross-sectional survey: Meaured	Random sample	24,604 in 1982	25-64	15.4	17.2	16.3
			1987	25-64	17.5	20.2	18.9
			1992	25-64	19.9	19.5	19.7
			1997	25-64	19.8	19.4	19.6
Gutiérrez-Fisac, et al (2000, Spain)[46]	Cross-sectional survey: Self-reported	Multistage stratified sampling in the primary units Simple random sampling in the secondary units (census districts)	14,676 in 1987	37-43	7.6	8.9	8.2
			7,004 in 1995/1997	37-43	12.3	12.1	12.2

Note: - = Data unavailable

Table 1.4 (continued)

Study (Year, Country)	Method	Sample	Number of participants	Age (years)	The prevalence of obesity (%)		
					Men	Women	Total
Europe							
Maillard, et al (1999, France)[47]	Cross-sectional survey: Self-reported	Multilevel stratified random sample	13,942 in 1980	20+	6.4	6.3	6.35
			15,106 in 1991	20+	6.4	7.8	7.1
Other developed countries							
Thorburn, A.W. (2005, Australia)[48]	Cross-sectional survey: Measured	Systematic sampling	1980	25-64	-	-	7.1
			11,247 in 1999-2000	25+	19.3	22.2	20.8
Kanazawa, et al (2002, Japan)[25]	Japan Society for the Study of Obesity (JASSO): Measured	-	150,000 in 1997	15+	1.6	2.7	2.2
The developing countries							
Rguibi, M. & Belahsen, R. (2007, Morocco)[49]	National survey: Measured	Random sample	41,526 in 1984/1985	20+	1.6	6.4	4.1
			14,028 in 1998/1999	20+	4.3	16.0	10.3
Madanat, et al (2007, Jordan)[50]	Cross-sectional survey: Measured	Random sample	2003	18+	-	13.0	-
			800 in 2004	18+	-	18.5	-
Wu, Y. (2006, China)[51]	National Nutrition and Health Survey: No details of BMI measured	-	140,022 in 2002	18+	-	-	7.1
Grabauskas, et al (2003, Lithuania)[52]	Cross-sectional survey: Self-reported	Random sample	3,000 in 2002	20-64	16.2	15.8	16.0
Galal, O.M. (2002, Egypt)[53]	Cross-sectional survey: Measured	Systematic sampling	5395 in 1994	20+	-	41.7 (U)	-
					-	27.6 (R)	-
			4,883 in 1998-1999	20+	20.0 (U)	45.2 (U)	32.6
					6.0 (R)	20.8 (R)	13.4

Note: - = Data unavailable

Table 1.4 (continued)

Study (Year, Country)	Method	Sample	Number of participants	Age (years)	The prevalence of obesity (%)		
					Men	Women	Total
The developing countries							
Puoane, et al (2002, South Africa)[54]	Cross-sectional survey: Measured	Stratified and systematic sampling	13,089 in 1998	15+	9.7	22.1	15.9
Ismail, et al (2002, Malaysia)[55]	National Health Morbidity Survey: Measured	Systematic sampling	28,737 in 1996	20+	4.0	7.6	5.8
Abdul-Rahim, et al (2001, Palestine)[56]	Cross-sectional survey: Measured	Systematic sampling	485 (U)	30-65	30.0	48.8	39.4
Misra, et al (2001, India)[57]	Cross-sectional survey: Measured*	Systematic sampling	532 (U)	18+	13.3	15.6	14.5
Monteiro, et al (2000, Brazil)[58]	National survey: Measured	Multistage stratified clustering sampling	15,585 in 1989	20+	4.7	12.0	8.4
			10,680 in 1997	20+	6.9	12.5	9.7

Note: - = Data unavailable, U = Urban, R = Rural, * = BMI > 25 kg/m^2

1.3.3.2 A UK issue

Obesity has tripled in the UK since the mid-1980s[59] resulting in the UK having the highest prevalence of obesity among European countries, thus it is a major problem facing the country – see Table 1.5. Obesity has risen in both men and women. In 1995 the proportion of the Scottish population that was obese was 1% higher in both men and women, compared with England. This trend has continued and in between 2003 and 2004, Scotland[60] had a higher prevalence of obesity than both England[6] and Wales.[8]

Table 1.5 The prevalence of obesity in the UK

Study (Year, Country)	Method	Sample	Number of participants	Age (years)	The prevalence of obesity (%)		
					Men	Women	Total
The United of Kingdom							
NHS (2009, UK)[9]	The Health Survey for England (HSE): Measured	Random sample	1980[59]	16+	6.0	8.0	7.0
			- 15,284 in 1993/1994	16+	13.2	16.4	14.8
			- 6,328 in 2005	16+	22.1	21.9	22.0
			- 11,920 in 2007	16+	24.0	24.0	24.0
Wardle, J. & Boniface, D. (2008, England)[61]	The Health Survey for England (HSE): Measured	Random sample	- 20,246 in 1993/1994	18+	13.4	15.8	14.6
			- 11,708 in 2002/2003	18+	22.7	22.4	22.6
Joint Health Survey Unit (2008, England)[62]	The Health Survey for England (HSE): Measured and self-reported	Random sample	- 24,115 in 2006	16+	24.0	24.0	24.0
Department of Health (2005, England) [63]	The Health Survey for England (HSE): Measured	Random sample	- 84,626 in 2004	16+	23.0	24.0	23.5
The Scottish Executive (2005, Scotland)[60]	The Scottish Health Survey: Measured and self-reported	Random sample	- 13,375 in 2003	16+	22.0	26.0	24.0
Welsh Assembly Government (2008, Wales)[64]	Welsh Health Survey: Self-reported	Random sample	2005/2007	16+	20.0	20.0	20.0

1.3.3.3 Summary of the worldwide prevalence of obesity

Many countries, especially developed countries such as the US, saw an increase in obesity between the 1970s and the mid 2000s that was generally greater for women than for men.[4, 35, 37, 65] Since 2000, several European countries have observed an increase in obesity similar to the US.[38, 40, 42, 43] In the UK,[61] the recent data shows a similar prevalence in both genders,[66, 67] similar to Finland.[45] All studies cited also suggested that obesity changed over time according to gender and age differences.[68]

1.3.4 Principles of prevention and treatment in obesity management

The principles of prevention and treatment in obesity management are to achieve and maintain healthy weight in individuals. Prevention strategies aim to help people maintain a healthy weight, and treatment aims to achieve and sustain weight loss in those who are already overweight. Public health policy for obesity is based on health promotion and combines many approaches such as encouraging environmental changes, educating obese people to balance healthy eating with physical activity, and identifying effective and culturally appropriate interventions. These approaches attempt to improve the prevention and treatment of obesity so that people are more likely achieve the healthy benefits of being a normal weight.

1.3.4.1 Principles of prevention in obesity

The rationale of obesity prevention is to tackle the development of either overweight or obese individuals' over time and the health consequences associated with obesity.[66] One approach, which is related to whole communities, is the population approach.[69] This population approach is based on health education programmes

promoting healthier lifestyles such as a reduction of saturated fat intake, smoking cessation, reducing serum cholesterol and reducing blood pressure. This approach also involves the cooperation of agricultural producers, food manufacturers and marketing companies in order to persuade consumers to make better choices. Additionally, it also requires healthcare professionals to be providing education on the appropriate behavioural changes needed to reduce risk of weight gain, especially advice targeted at local food preferences and the promotion of leisure facilities to improve exercise habits.[66, 70]

1.3.4.2 Principles of treatment in obesity

The goals of obesity treatment are to achieve and to maintain weight loss. The requirement for obesity treatment is based on an assessment of patients' need to reduce their weight. Patients' treatment selection for obesity is guided not only by the individuals' BMI and health condition but also by their previous weight loss attempts. Patients should select their treatment options with consideration of safety, efficacy and cost.

This treatment recommendation can be seen as a three-stage process:[70]

1. Stage One: Classification decision

   People are divided into four levels of BMI classification.

2. Stage Two: Stepped-Care decision

   When one approach is unsuccessful a more intensive intervention may be justified, such as a weight loss programme, taking into consideration cost as risk of side effects.

3. Stage Three: Matching decision

   This stage is a final treatment selection that is based on the individuals' previous weight loss attempts, treatment preferences and need for weight reduction.

In addition, selecting treatment is also dependent on patients' previous weight loss attempts which requires a multimodality approach through both reducing energy intake and increasing energy output.[70] Strategies for reducing energy intake consist of diets and medicines.

Diets

The diet approach aims to reduce fat consumption and provide low energy density in the diet. For example, low carbohydrate diets are using foods with a lower glycemic index or lower glycemic load thus reducing the total amount of carbohydrate. High protein diets are part of low-fat intake that could enhance weight maintenance. Very low-calorie diets (VLCD) or very low energy diets are formulated to substantially reduce the caloric intake. The lower the energy intake, the more rapid the weight loss. This approach is used for long-term weight loss and weight maintenance, and also can be used in combination with reducing total fat intake, reducing portion size, reducing energy density, reducing calories and increasing fruit and vegetable intake.[70]

Anti-obesity medicines

Anti-obesity medicines are less commonly used and are yet to be established as acceptable in the context of the long-term safety.[70] When weight-loss medicines are stopped, weight may be regained. This approach is used when patients become less motivated or find it difficult to persist with the long-term changes in eating and activity, and they need to lose weight and avoid weight regain to reduce their health risks.[71]

Exercise

Exercise is the single best predictor of long-term weight maintenance but is less likely to predict weight loss in the short term.[70] Patients who aim to achieve the long-term weight maintenance should be physically active for 30-60 minutes per day on a least five days per week.[70]

In addition, the treatment of obesity involves changing patients' long-term behaviour, changes that will include self-monitoring, environmental modification and social support[70] – see Table 1.6.

Table 1.6 Behaviour change for weight loss

Behaviour change techniques	Example	Suggestions for implementation
Self-monitoring	Monitor energy intake	Calorie counting/restriction, daily food record
	Keep track of exercise activity	Set realistic goals for time and distance walked e.g. increase walking in the daily life or using stairs instead of a lift
Environmental modification	Permanent change in eating habits	Eating more fruits and vegetables, limiting sweetened drinks/not adding sugar to drinks
	Be mindful of weight loss goals while grocery shopping	Buy fruits and vegetables
	Reduce consumption of food outside the home	Avoiding take away food, avoiding eating out at restaurants
	Increase physical activity	Increase walking in the daily life, going to the gym or using stairs instead of a lift
Social supports	Family	A family can help to increase exercise and avoid temptation.
	General practice or other health care professionals	Refine optimistic strategies, facilitate follow-up appointment

Source: Thompson WG, et al. Treatment of Obesity.[70]

A combination of the weight loss strategies is more likely to succeed than any single strategy alone. GPs and other health care professionals can assist patients' efforts to reduce portion size, count food calories and plan menus. To increase the chances of success, strategies for weight loss should be tailored to the patient through discussion between the patient and their GP.[70]

1.3.5 Anti-obesity medicine

Since 1998, there has been a dramatic increase in the prescribing of anti-obesity medicines. Anti-obesity medicines are not first line treatments but are recommended for patients who have not been successful with other treatments, such as lifestyle modification. A management pathway for the appropriate prescribing of anti-obesity medicines is shown in Figure 1.1.[16]

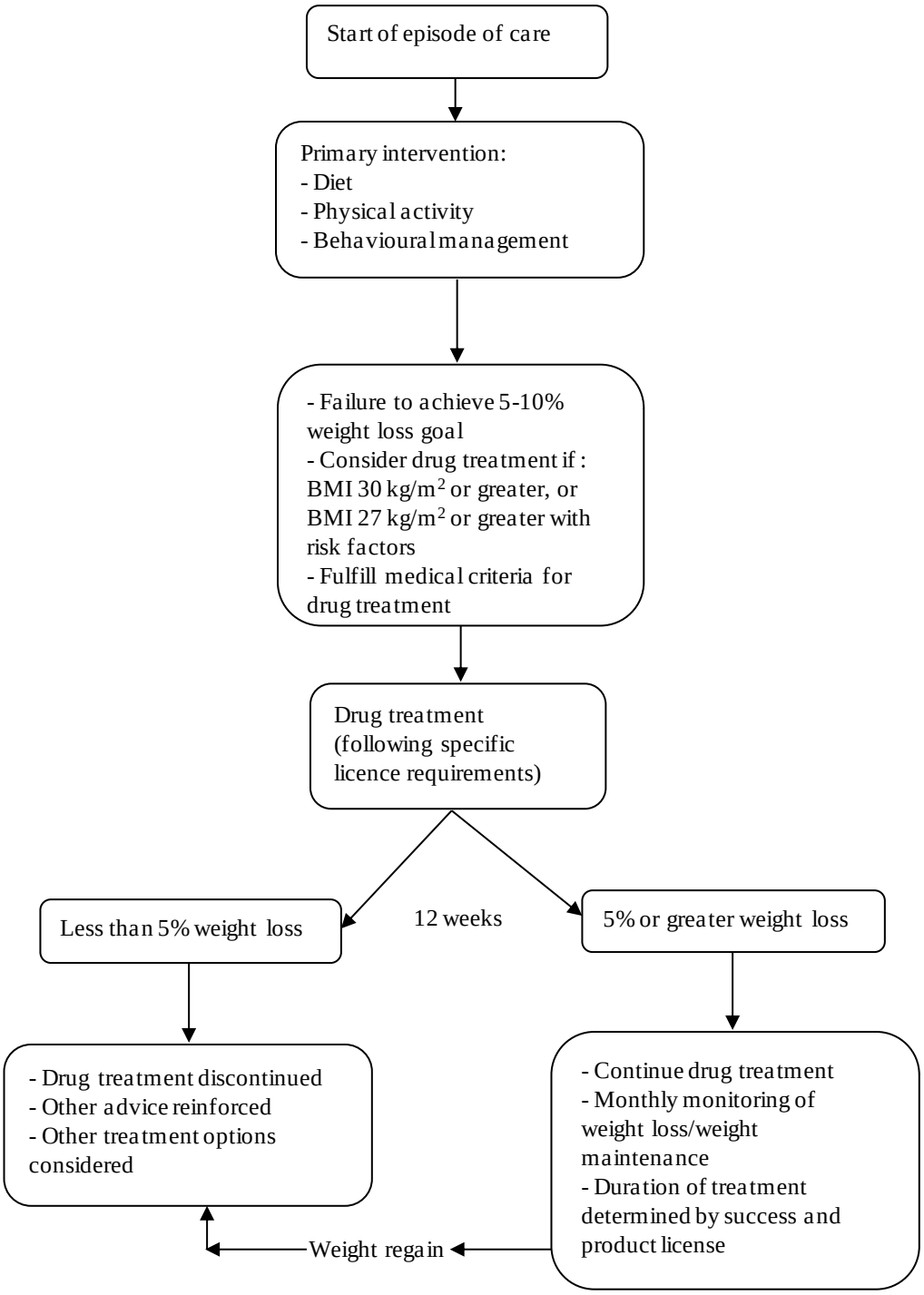

Figure 1.1 A management pathway for the appropriate prescription of anti-obesity medicine

Source: Anti-obesity Drugs: Guidance on Appropriate Prescribing and Management: A report of the Nutrition Committee of the Royal College of Physicians of London.[16]

1.3.5.1 Orlistat 120 mg (Xenical®)

Currently, there is only one recommended anti-obesity medicine which acts on the gastrointestinal system. Orlistat 120 mg[72, 73] was launched in the UK in December 1998[74] – see Table 1.7.

Table 1.7 Orlistat used in the treatment of obesity

	Orlistat 120 mg (Xenical®)
Indications	A potent inhibitor of both gastric and pancreatic lipase, reduces the absorption of approximately 25% of dietary fat. The approved indication is alongside a reduced-calorie, low-fat diet and exercise programme. Overweight or obese adults aged 18-75 years with a 1. BMI of 28 kg/m^2 or more in the presence of significant comorbidities 2. BMI of 30 kg/m^2 or more. Lose an initial minimum of 2.5 kg with diet and physical activity Within 3 months, weight loss should be around 5% of body weight and 10% after 6 months Can be continued longer than 12 months after a discussion between patient and professional
Cautions	May impair absorption of fat-soluble vitamins
Contra-indications	Chronic malabsorption syndrome, cholestasis, breastfeeding and pregnancy
Interactions	Fat-soluble vitamins such as vitamins A, D, E, K and beta-carotene take at bedtime to help ensure adequate vitamin intake Oral anticoagulants including warfarin, thyroid medicines, amiodarone, oral contraceptives and antidiabetic agents
Side-effects	Altered bowel habits: Include fatty oily stool (steatorrhea), gas with oily spotting, faecal urgency and faecal incontinence Vitamin malabsorption
Dose	Adults over 18 years: Take orlistat during or up to an hour after each meal containing fat Daily dose: 120 mg 3 times daily Note: The dose of orlistat can be omitted when patients miss a meal or food contains no fat.

Source: Midland Therapeutic Review & Advisory Committee (MTRAC). *Summary Sheet for: Orlistat (Xenical®) for the treatment of obesity*: Department of medicines management, Keele University, March 2001.[74]

There has been a study examining the effectiveness of using orlistat 120 mg in combination with a non-pharmacological intervention, which suggested that the group of patients who received a personalised reduced energy diet in discussion with a family physician and dietician as well as orlistat, achieved a greater percentage weight reduction than the group of patients who only received the reduced energy diet. This shows that prescribing orlistat in combination with other approaches is effective in the management of obesity.[13]

1.3.5.2 Supply of prescription anti-obesity medicines

The previous studies reviewed, that discussed the supply of prescription anti-obesity medicines, were mainly in relation to NCWLPs – those offered free of charge to the user (as defined on page 3).

A study by Kaya et al.[75] found that the efficacy of sibutramine, orlistat or combination of both medicines on short-term weight management in obese patients was significantly better than dietary regimens alone. However, they were not able to establish whether one therapy was superior to the other. A US study of anti-obesity medication use by Stafford and Radley[76] found that orlistat prescribing was higher than sibutramine, even when it was newly released in 1999. Additionally, patients demonstrated increases in heart rate and blood pressure as side effects of sibutramine.[76] However, sibutramine,[77] which acts on the central nervous system, was withdrawn in the European Union in early 2010.[78]

Similar studies in the UK have shown that orlistat is the most frequently prescribed anti-obesity medication in the UK. The number of prescriptions written for orlistat

rose 36-fold from 17,800 to 646,700 between 1998 and 2005 compared with sibutramine where the increase was 4-fold from 53,393 to 227,000 between 2001 and 2005.[79] Until recently orlistat has only been available on prescription or under a patient group direction (PGD) in pharmacist-led weight management clinics. In April 2009, orlistat 60 mg was reclassified in the UK as a pharmacy medicine (P).

Derosa et al.[80] found that in obese patients with hypercholesterolemia, orlistat significantly reduced BMI, waist circumference (WC), body weight (BW), systolic blood pressure and diastolic blood pressure at 6 and 12 months compared with baseline.[80] A study adding orlistat to a weight management programme (personal diet and meetings with physicians and dieticians) resulted in patients being more likely to achieve their weight reduction goals than those on the programme alone.[13] In contrast Poston et al.[81] found no differences in patients on orlistat alone compared with combining this with brief counselling. Orlistat has also been shown to improve physical ability in patients with chronic kidney disease (CKD) after 12 months, alongside reductions in BW and WC.[82] Similarly in overweight patients with type 2 diabetes other benefits in addition to weight loss have been found for orlistat - namely reductions in fasting blood glucose, low-density lipid (LDL) cholesterol and blood pressure.[83, 84] Overweight patients who achieved weight loss of ≥10% of their initial weight with orlistat at 12 months, continued to lose more weight at 18 months.[14]

Patients who used orlistat and achieved a considerable weight reduction also benefited from decreased BW, blood pressure and fasting blood glucose at three and six months.[75, 80] Most studies measured those changes before and after treatment, and also followed up at 12 months as the end point.

1.3.5.3 Supply of over-the counter Orlistat 60 mg (Alli®)

Orlistat 60 mg (Alli®) has been approved for OTC supply in the management of obesity.[85] It was launched in the US in 2007 and has been used by millions of people.[86] In the European Union, orlistat 60 mg was approved in October 2008 and marketed in the UK from April 2009. OTC orlistat is licensed for use in overweight people (BMI of 28 kg/m^2 or over), aged 18 years old or over and taken in conjunction with a mildly hypocaloric diet and low fat diet. Efficacy is similar to orlistat 120 mg – see Table 1.8. Patients taking orlistat 60 mg mostly lost at least 5% body weight within the first year of treatment although this weight loss was less likely than if treated with orlistat 120 mg. It could be concluded that the efficacy of prescription strength orlistat is not different from OTC strength orlistat in the treatment of obesity. Pharmacists have been issued with guidance about sale of OTC orlistat which includes eliciting information from patients, ensuring the medicine will be safely used and advising about adverse effects[87] – see Table 1.8.

OTC orlistat is available for pharmacists to supply directly to their patients. OTC orlistat is another product where community pharmacists can become involved with longer term therapy and monitoring patients' progress. The OTC availability allows patients to have more choice in the methods used to reduce their weight and

furthermore governments can potentially save health service costs related to reductions in prescribing.[88-90]

Table 1.8 Summary of the efficacy of orlistat 60 mg TID in the treatment of obesity

Study	No. of patients	Dose (mg)	Duration (mo)	BMI (kg/m^2)	% of Patients with ≥ 5% weight loss	Comments
Hauptman, et al.[91]	212 P		0-12	30-44	31	Patients treated taking orlistat 120 mg were more likely to lose 5% of their initial weight than those taking orlistat 60 mg in year 1. However, both groups lost significantly more weight than placebo.
	213 O	60			49	
	210 O	120			51	
	122 P		12-24	30-44	24	In year 2, patients in both groups lost the same percentage of body weight.
	154 O	60			34	
	151 O	120			34	
Rössner, et al.[92]	244 O	120	0-12	28-43	63	Patients taking orlistat 120 mg and 60 mg significantly lost 5% from the first weight more than those with placebo.
	242 O	60			63	
	243 P				44	
	159 O	120	12-24	28-43	65	Patients with both orlistat 120 mg and 60 mg significantly increased the weight loss in year 2.
	140 O	60			56	
	136 P				38	
Hill, et al.[93]					Body weight regain (%)	Patients treated with orlistat 120 mg regained less weight than others.
	181 O	120			32	
	173 O	60			47	
	187 O	30	0-12	28-43	53	
	188 P				56	
Anderson, et al.[94]					% of baseline weight lost	The efficacy of orlistat was greater than placebo.
	196 O	60	4	25-28	4.2 (3.6 kg)	
	195 P				2.6 (2.2 kg)	

Note: O = Orlistat, P = Placebo

Orlistat 60 mg (Alli®) is unlike other products available without prescription for weight loss because it is a proven medicine that has been shown to be effective alongside a reduced-calorie, low-fat diet and exercise programme.[95, 96] Studies of orlistat found that patients who used this drug following the dosing directions tolerated the medicine well and the safety was similar to the prescription dose.[94] Although patients reported gastrointestinal (GI) effects such as diarrhoea, abdominal pain, flatulence, nausea/vomiting, rectal discharge and faecal incontinence, they still reported high satisfaction with orlistat in weight loss therapy. Orlistat is not only recommended as a safe and effective medicine in treating obesity but for its benefit in improving quality of life of those patients.[97, 98]

1.3.5.4 Supply via Patient Group Direction

Definition of Patient Group Direction

A Patient Group Direction (PGD)[99] is a written direction relating to supply and/or administration of a licensed medicine or prescription only medicine (POM) to persons and is signed by a doctor or dentist and a pharmacist.

Treatment issued under a PGD can be provided by a specified range of health care professionals such as a pharmacist or nurse, without the patient first seeing a doctor or dentist. PGDs are usually a local arrangement between groups of health care professionals looking after the health needs of the local area; however they can also be national arrangements. Services using PGDs can be developed in the private sector, as in Boots pharmacies.[99] The BPWLP is a national PGD which aims to assist clients to lose weight. PGDs are required to set out in detail the conditions under

which a POM can be supplied without prescription including the details of the health care professionals who have made the agreement – see Box 1.1.

A PGD contains information as follows:

- The name of the body to which the direction applies
- The date that direction comes into force and expires
- A description of the medicine
- The clinical conditions
- A description of patients who are excluded from the treatment under the direction
- A description of the circumstances under which further advice should be sought from a doctor (or dentist, as appropriate) and arrangements for referral made
- Appropriate dosage and maximum total dosage, quantity, pharmaceutical form and strength, route and frequency of administration, and minimum or maximum period of the medicine should be administered
- Relevant warnings including potential adverse reactions
- Details of any follow-up action and the circumstances
- A statement of the records to be kept for audit purposes

Box 1.1 Information required in private Patient Group Directions for pharmacists' authorisation to supply medicines

Source: Boots. Boots Pharmacy Weight Loss Programme (BPWLP) overview.[99]

Boots Private Patient Group Direction of Orlistat 120 mg

The purpose of the PGD is to enable pharmacists to provide orlistat to patients within the setting of a pharmacy authorised by the independent medical agency (IMA). Boots pharmacies have been able to provide customers with greater access to treatments through private PGDs since registering as an IMA with the Healthcare Commission (HCC) in 2003. To deliver private PGDs, a pharmacist must receive authorisation from the IMA after completing specific training and being assessed by an authorised sign-off person (ASP).[99]

Boots pharmacy offers private PGDs to provide easier access for customers to appropriate and effective treatments for a wide range of conditions and to extend the pharmacist's and team members roles to further develop their skills and knowledge in order to offer a new professional service.[99] Customers can have access to well trained healthcare professionals offering a high standard of service and advice and following-up appointments at the end of month one, three, six, 12, 18 and 24 – see Appendix 1.

1.3.6 Pharmacy practice in the UK

Over 90% of both healthy and ill people visit community pharmacies in the UK.[24, 100] Community pharmacies are the most accessible site for healthcare services such as health promotion in the community.[101] As a consequence, pharmacy has the potential to maintain the combination of safety, accessibility and reliability of medicine supply to extend the role of the pharmacist.[102]

1.3.6.1 The traditional role of the pharmacist

Pharmacists can assist patients in making healthy lifestyle choices due to their credibility as health professionals and their accessibility in the community pharmacy.[103] In the UK community pharmacists provide both NHS and commercial services.[104] Anderson[104] reviewed how the role of the community pharmacist has been changed in professional practice and also found that pharmacists were involved in health promotion and training for their future role. In pharmacy practice, health issues have increasingly been promoted by pharmacist[105, 106] – see Table 1.9.

Table 1.9 Examples of traditional and newer roles of the pharmacist

Traditional roles of the pharmacist	Newer roles of the pharmacist
- Dispensing prescriptions written by doctors - Supplying quality medicines - Ensuring medicines supplied and prescribed is legal and appropriable - Advising patients about medicines that included taking medicines and interactions with drug and food	Essential services - Dispensing, repeat dispensing via electronic prescription service (EPS) - Disposal of medicines - Promotion of healthy lifestyles and self care for patients with minor ailments - Advising and signposting other healthcare professionals about safe and effective medicines use for patients - Supervising the production and preparation of medicines
	Advanced services: Providing services to patients such as medicine review, smoking cessation, blood pressure, cholesterol measurement, etc.
	Enhanced services:[107] Providing local services such as minor ailment schemes, supplementary prescribing, sexual health care

In order for pharmacists to achieve some of these future roles they will need to work more closely with GPs and other health professionals. Examples of such services are:[102]

- Health checks in pharmacies – since 2004 Boots pharmacies have offered cardiovascular health checks by monitoring people who have been diagnosed with a cardiovascular condition by their GP.
- Medicines supply services such as smoking cessation support with NRT (Nicotine Replacement Therapy) supply, influenza vaccinations and Chlamydia screening and treatment.
- Self-care support. Medicine use reviews and Internet support for public access about health.

1.3.6.2 The role of the pharmacist in obesity management

Pharmacists can play an important role in obesity management. Obesity is considered an area where pharmacists can contribute to the health of both individuals and the population – see Box 1.2.

The role of the pharmacist in combating obesity has been described as follows:

- Providing advice on risks from therapy, benefits of treatment, selection of weight-loss agents, appropriate counselling and behavioural change such as healthy eating and increasing daily activity
- Supporting people to lose weight and promotion of healthy lifestyles to prevent people becoming overweight and obese
- Communicating with customers about the health advantages of losing weight
- Being sympathetic to people who are suffering from chronic disease
- Reinforcing the importance of changing their lifestyle to improve and maintain weight loss
- Increasing frequency of people contact that can improve the success of weight loss and maintenance efforts
- Signposting by informing patients of other resources such as the relevant websites about weight loss products and making referrals if necessary as having high blood pressure or blood glucose level
- Providing the safe supply of anti-obesity medicines:
    - Warning about adverse effects, drug interactions, the potential impurities of herbal products and product utilization
    - Identifying and monitoring appropriate individual to use weight-loss medicines to maximise safety and efficacy
- Collaborating with other health care professionals

Box 1.2 The role of the pharmacist in obesity

Source: Bottorff M. Role of the Pharmacist.[108] Chambers R, et al. *Supporting Self Care in Primary Care*. Oxford: Radcliffe Publishing Ltd, 2006.[109]

Boots have additional requirements for their employed pharmacists providing weight management consultations. Pharmacists are required to become familiar with the process which involves counselling and paperwork, a clearly understanding of record keeping and the till process, learning how to effectively manage their time and requiring store as What Good Looks Like (WGLL).[99]

Pharmacy providing the service should comply with What Good Looks Like (WGLL) requirements as set out by Boots. The WGLL checklist includes:[99]

- The consultation room: Appropriate and ready for use
- Support staff: Adequately trained and aware of the programme
- Dispensary staff: Clearly make the necessary records
- All necessary equipment: Available
- Appointment diary: In place
- Patient records: Filed appropriately and confidentially
- Pharmacist: Appropriate clinical training and understanding the PGD complaints procedure
- Engaging customers by advertising (including leaflets) or through promotion by a satisfied customer or partner, pharmacist, team member, or healthcare professional.

Pharmacists provide the full obesity management consultation under four categories, which are 1) customer service: welcome and general conduct during consultation, 2) management of the consultation: smooth flow of the consultation with target times met, 3) consent and customer understanding: proper consent from patients and ensure their understanding and 4) information: delivering, seeking and recording.[99]

1.3.6.3 Pharmacy medicines

The 1968 Medicines Act defined pharmacy medicines that can be obtained without a prescription form under the supervision of a qualified pharmacist. Since 2009, politicians have responded to a perceived public demand for readier access to medicines, and increasing numbers of medicines have been reclassified from POM (prescriptions-only medicines) to P (pharmacy medicines). Only pharmacies can sell pharmacy medicines, and pharmacists must supervise the sale.[110]

Most pharmacy medicines are used in the treatment of minor ailments or injuries, for health promotion and to assist patients in making healthier lifestyle choices such as orlistat for obesity.[110]

1.3.6.4 Pharmacist-led weight management clinics

In the UK, obesity is a huge public health issue and reducing obesity is a health promotion priority. The 2008 Government White Paper potentially included the community pharmacy as a source for weight loss programmes.[111] Pharmacists contribute to weight management as a part of a health check in height, weight, blood pressure and blood sugar, and the provision of advice and support by following the scheme of using patient group directions to facilitate the supply of prescription-only medicine.

A systematic review by Gordon et al.[18] found that the effectiveness of long-term (12 months) community pharmacy weight management interventions showed a mean weight loss from 1.1 to 4.1 kg. They also reported the clinically significant weight

loss was five to six percent of the initial body weight at three and six months. Studies in this review showed unclear evidence for the effectiveness of weight management programmes in the community pharmacy. All weight loss interventions were delivered by at least one pharmacist with or without support staff involvement. This review also indicated some studies with high-quality of community pharmacy-based weight management.

1.3.7 Weight loss programmes

1.3.7.1 Weight loss strategies

Weight loss occurs when there is a negative energy balance, that is, energy expenditure is greater than energy intake from food and drink. There are a wide range of weight loss strategies available from health professionals to help patients lose weight. Table 1.10 provides the advantages and disadvantages of the most common weight loss strategies that include CWLP such as Weight Watchers (WW) and Jenny Craig (JC).[112]

Table 1.10 Summary of weight loss strategies

Weight loss strategies	Advantages	Disadvantages
Low carbohydrate diet (< 20 g/day)	Increase in protein intake Show a greater weight loss than low fat diets at 6 months	Increase malnutrition because of cutting out some of the core food elements Not recommended in patients with osteoporosis, kidney disease or LDL cholesterol
Low fat diet (30-50 g/day)	Decrease dietary fat intake without reducing volume of food intake	Reduce good fats as well as bad fats May increase sugar content and glycaemic index
Portion control (calorie controlled for all foods)	Use portion plates and select smaller packages Provide the pictorial guides to simply educate overweight or obese people for all food levels	May face to the oversized packaging, dinnerware and utensils Require education in appropriate portion sizes
Meal replacement: - Low energy diet: 3.4-5.0 mj/day - Very low diet: < 3.4 mj/day	Good for such people who have difficulty choosing or preparing meals and controlling portions Well designed programme for a comprehensive weight loss programme	Lack of following up from some weight loss programme May not improve long term dietary behaviours Reducing energy intake makes metabolism slow and needs to compensate metabolic mechanisms
Exercise	Regular exercise is good for health Can be free and enjoyable Decrease risk of mortality that related to BMI	Unable to achieve weight loss if standing alone Exercise over an hour of brisk walking per day may be impractical without dietary modification
Behavioural intervention	This strategy is suited to individual needs	Need dietary change
Medicine e.g. Orlistat	Be effective when using in conjunction with diet, exercise and lifestyle modification	Need to combine with other therapies Need evidence for long term safety and effectiveness Side effects Expensive

Source: Clark A, et al. Overweight and obesity – use of portion control in management.[112]

1.3.7.2 Commercial weight loss programmes

Defining commercial weight loss programmes

CWLPs are defined as structured commercial weight loss programmes provided to the public by an organisation delivering the intervention for profit, including the provision of vouchers or partial subsidies. Examples include:

- US: WW, JC, Health Management Resources (HMR), Nutrisystem, eDiets.com,[113] LEARN
- UK: Slimming World (SW), Rosemary Conley (RC), LighterLife (LL)
- European country: Weight Balance (Finland)

US commercial weight loss programme

In the US, approximately 55% of Americans were considered overweight or obese in 1998.[114] Millions participated in commercially available weight loss programmes.[115] In 1987, there were approximately 13,000 US weight loss programmes and products such as commercial weight loss clinics, physician-supervised programmes, low-calorie foods, artificial sweeteners and diet books.[114] These programmes are directly purchased by consumers or provided through health insurance cover.

In the US, there are Federal Trade Commission[116] guidelines for providers of CWLPs – these cover content, pricing and effectiveness of programmes.[114, 115]

In the US many commercial programmes involve diet and exercise such as Weight Watchers (WW) and Jenny Craig (JC) or meal replacement such as Health Management Resources (HMR), eDiets.com and LEARN. Examples of these programmes are described below.

Weight Watchers

WW is the largest worldwide CWLP and aims to help members succeed in achieving their weight loss goals. This programme not only provides dietary counselling and group support through weekly meetings but also has a range of food products which clients can purchase in supermarkets. WW additionally provides support via electronic applications such as computers or smart phone. Meeting leaders are trained by the company for at least 6 weeks about setting weight loss goals, achieving and maintaining weight loss, the use of dietary supplements and increasing exercise. After training, group support leaders are able to advise their clients and refer clients to their physicians, if needed. Costs of WW are covered by a membership fee and weekly meeting fees.

Jenny Craig

JC is the second largest CWLP and aims to help clients to succeed in their weight loss by changing their lifestyle and eating habits. This commercial programme also provides individual dietary counselling and pre-packaged meals. Once clients reach their weight loss target, they no longer need to rely on the programmes or consultations in order to maintain their healthy lifestyle. Nevertheless, they may continue to attend this programme for their weight maintenance. The standard plan of this programme lasts one year. Additionally, the programme offers telephone support

24 hours a day, 7 days a week. Costs of JC are covered by a membership fee and daily food purchases from the company.

Health Management Resources

HMR is a meal replacement weight loss programme introduced in 1983 and aims to establish medical and behavioural weight loss interventions in hospitals, medical schools and medical practices. This programme offers three dietary options for weight loss which includes a VLCD, a combination of meal replacements and conventional foods, and a telephone-based programme. The costs of HMR are covered by fees for the 12 week treatment programme, fees for the initial history, physical examination, physician visits, laboratory tests and programme classes, in addition to the meal replacement purchases that clients make.

eDiets.com

eDiets.com is an Internet-based commercial programme that offers professional dietary, nutritional and exercise advice through the website. This programme also prescribes an individualised hypocaloric diet for 12 weeks. Clients who participate in this programme are required to purchase and prepare their own meals while the programme provides additional services within the 13-week membership package, weekly online chats and individualized e-mail counselling from experts.[114]

LEARN

The LEARN programme for weight control is a lifestyle behaviour-change programme. LEARN stands for the five key components which are Lifestyle, Exercise, Attitudes, Relationships and Nutrition. The LEARN programme also

provides supplements to other weight management programmes including commercial ones. The LEARN programme consists of 16 weekly lessons that address different aspects of weight control, following a commencement lesson (including a master list of 158 lifestyle change techniques, the Weight Loss Readiness Test and a comprehensive index) and offers group programmes with health professional instructors and one-on-one counselling.[117] This programme is the first training and certification programme to offer multidisciplinary training in both weight and stress management. It has also been used as a self-study or self-help programme in support groups with a professional counsellor or in individual face-to-face counselling with a health professional.

Summary of US commercial weight loss programmes

US CWLPs include the programme components (diet, physical activity and behaviour modification), effectiveness of the programme and costs.[116] All CWLPs mentioned about price because people can consider price and ultimate benefits if/as they prepare themselves to attend the programme.

UK commercial weight loss programmes

In the UK, CWLPs are a widely available option for overweight and obese people.[17] Weight loss programmes have also been delivered in partnerships with NHS primary care organizations such as Slimming World (SW),[118] Rosemary Conley (RC) and LighterLife (LL).[119]

Slimming World

SW is a commercial slimming organization with weekly group sessions led by consultants.[118] Members are able to lose weight through a combination of its 'Food Optimising' eating plan, moderate activity through the 'Body Magic' programme, group support and shared experience with other slimmers by encouraging behaviour change. The cost of being a member of Slimming World is approximately £4.95 per week.[120]

Rosemary Conley

RC is the name of an English business woman who is the founder and president of RC Diet and Fitness Clubs.[121] This weight management club is one of biggest three weight loss organizations alongside SW and WW.[122] This CWLP aims to provide overweight and obese people with assistance to help them lose weight and to encourage both groups to adopt a healthy lifestyle. This programme also includes diets and physical activity. Prices of RC depend on membership status and treatment duration.[122]

LighterLife

LL simply aims to assist overweight and obese people to lose weight. This programme combines nutritionally balanced weight loss foods with VLCD meal plans and motivation by counselling. The initial phase lasts for 100 days and during this time people use the food packs provided and attend weekly counselling sessions. If they wish to lose more weight after the initial phase, they can continue with this. When they have achieved their target weight, there is a long-term weight maintenance programme where they slowly return to conventional food whilst

reducing reliance on and use of the food packs. Costs of LL include food packs and counselling sessions, and cost members approximately £66 per week.[123]

Summary of UK commercial weight loss programmes

UK CWLPs emphasise diet, physical activity and maintenance support. Details of three CWLPs above have included price because people can consider costs and ultimate benefits before they decide whether or not to attend the programme.

Commercial weight loss programme in other countries

Lastly, CWLPs in other countries include programmes such as the Finnish provided Weight Balance® programme.

Weight Balance

Weight Balance is a mobile phone-operated weight-loss programme, launched in Finland in 2001.[124] This programme provides a daily calculated diet and physical activity plan for energy requirements of participants. Weight Balance also advises on reducing participants' food intake by leaving out unnecessary foods. Participants set their weight loss goal for 12 weeks and after they have reached their target, they can switch to a weight maintenance programme.

In the UK, little research has been conducted to evaluate the effectiveness of CWLPs. The effects on weight reduction, changes in BMI, blood pressure, blood glucose and presence or absence of risk factors still have to be established. There is a gap in the literature concerning research assessing the provision of CWLPs from community pharmacies. There are currently pharmacist-led clinics for weight

management. For example, many larger Boots stores offer a weight management programme which includes the provision of lifestyle advice, regular weight checks and the supply of orlistat via a private PGD. The next section describes the Boots Pharmacy Weight Loss Programme.

1.3.7.3 Boots Pharmacy Weight Loss Programme

BPWLP[99] is a programme designed to help medically overweight or obese customers lose weight and is led by a pharmacist. This CWLP uses orlistat 120 mg in combination with advice and support on diet and physical activity. Customers who participate in this programme can decide to attend consultations at the pharmacy at monthly or 3 monthly intervals. The cost of the BPWLP to the patient is £62.50 and £125.00 for four and 12 weeks, respectively. There is no membership fee; however, if customers have a Boots Advantage Card, they will receive discounts for attending this programme[99] – see Table 1.11. This programme can be used as a model for weight management in community pharmacies, using PGDs to supply orlistat 120 mg outside the scope of the NHS.[125]

Table 1.11 Comparison of Boots Pharmacy Weight Loss Programme and NICE obesity treatment recommendations

NICE pathway for the appropriate prescription of anti-obesity medicine	Boots Pharmacy Weight Loss Programme	How BPWLP meets NICE standards
Considering drug treatment if: BMI ≥ 30 kg/m^2 or greater, or BMI ≥ 27 kg/m^2 or greater with risk factors	✓	Having BMI ≥ 30 kg/m^2 or ≥ 28 kg/m^2 with at last one co-morbidity related to risk factors
Fulfilling medical criteria for drug treatment (orlistat 120 mg)	✓	Providing supply of orlistat via private PDG combination with pharmacist's consultation Having exclusion criteria such as pregnant, breast-feeding, insulin-dependent diabetes, any present liver; gall bladder or jaundice, surgery for weight loss, gastrointestinal malabsorption problems, sensitivity to orlistat and any concomitant medication
Weight loss < 5% of the initial weight - Drug treatment discontinued - Other advice reinforced - Other treatment options considered	✓	Customers who failed to achieve their minimum weight loss required discontinuing the programme and could attend this programme after 12 weeks.
Weight loss ≥ 5% of the initial weight - Continue drug treatment - Monthly monitoring of weight loss/weight maintenance - Duration of treatment determined by success and product license	✓	Customers decided to continue the weight loss programme if they had their weight loss at least 5% of the initial weight and have followed-up maximum two years.
Patients' age 18 years and older	✓	Patients' age between 18 and 82 years

BPWLP was launched in May 2005 and has been available in over 200 stores since 13 July 2009 in the UK offering the service which consists of:

- A consultation and assessment by an authorised pharmacist
- Comprehensive support and advice on healthy eating and physical activity
- Supply of a prescription only medicine (orlistat 120 mg, Xenical®)

- Discount on Boots branded low calorie products (Shapers) and Exercise equipment for Advantage card holders only

Based on the criteria of Boots Pharmacy Private PGD, customers eligible for BPWLP should have a BMI equal to or greater than 30 kg/m^2 or 28 kg/m^2 with at least one co-morbidity related to risk factor. Exclusion criteria are pregnancy, breast-feeding, insulin-dependent diabetes, liver disease; gall bladder or jaundice, surgery for weight loss, gastrointestinal malabsorption problems, sensitivity to orlistat and any concomitant interacting medicines such as amiodarone, acarbose or ciclosporin.

All customers who met the inclusion criteria had the service explained before deciding whether or not to participate. At the initial visit, the pharmacist recorded each customers' history of any previous weight loss attempts, inclusion and exclusion criteria, advice given for orlistat, outcome of consultation, blood pressure, blood glucose, height (metres/feet and inches), weight (kg/lbs), BMI, minimum weight loss required at three months (5% of the initial weight at programme entry), customers' consent, date of visits, date and amount of the supply of orlistat and date of the follow-up visit. The pharmacist followed customers with monthly appointments and monitored their weight loss, BMI, diet, exercise and side effects.

After 12 weeks customers can decide to continue the weight loss programme if their weight loss was at least 5% of the initial weight. However, customers who failed to achieve this minimum weight loss were required to stop the programme. The baseline and follow-up consultations with customers were performed by the pharmacists, with referral to a doctor if appropriate.

Managing obesity in Boots Pharmacy Weight Loss Programme

The four elements, which are provided for pharmacists to guide them in the provision of the BPWLP, consist of:

- Details of the measurement and recording of data the initial consultation together with the type of advice to be offered
- Guidance on the information to be provided to the clients about orlistat including how it works and how to take it
- Details of measurements and records to be made at follow-up visits
- Information about ongoing weight loss advice and how to continue to motivate clients to lose weight

The client's journey through the BPWLP is shown in Figure 1.2. This guide is available for store staff to help them guide clients through the service.

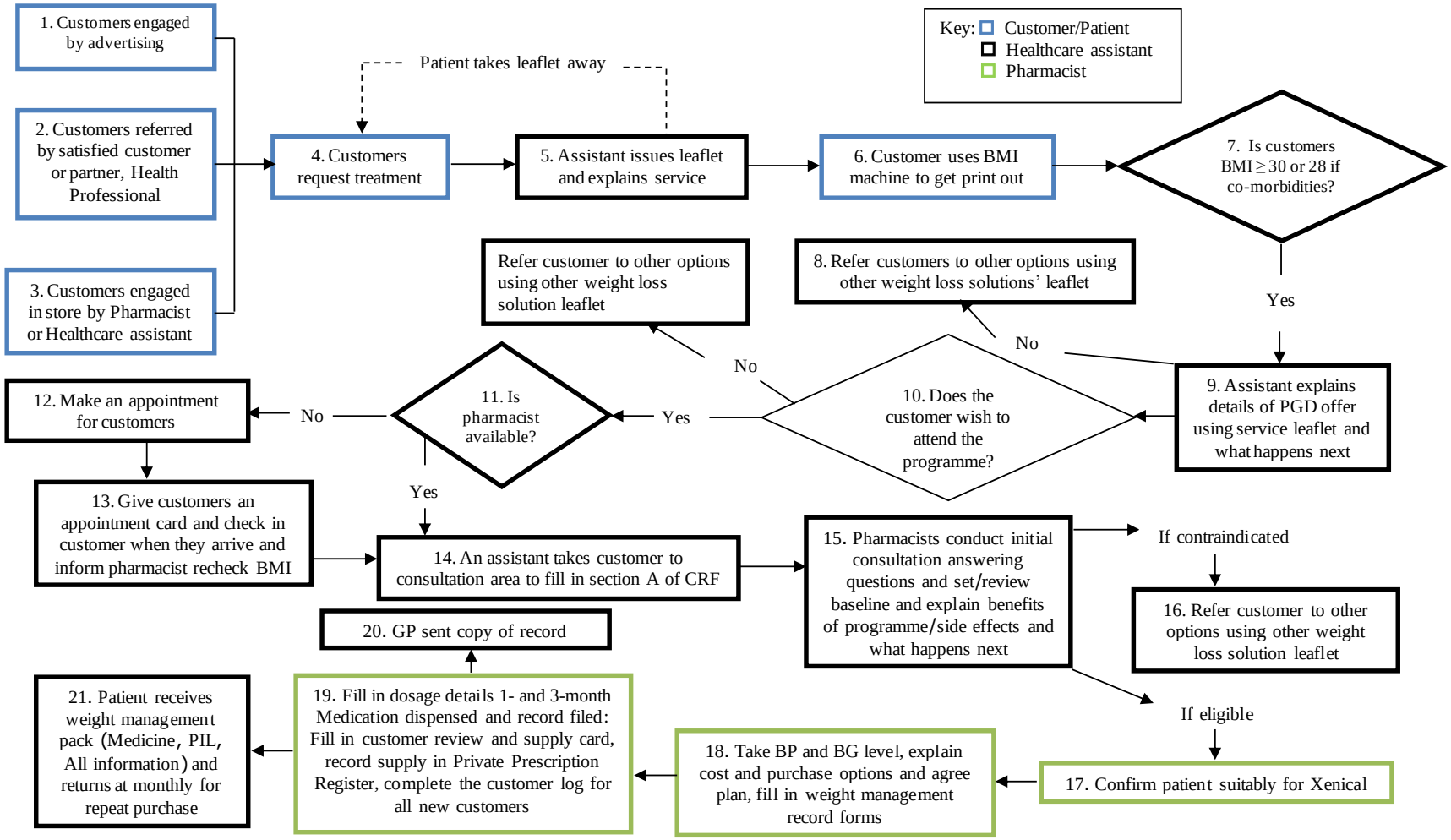

Figure 1.2 Client's journey of Boots Pharmacy Weight Loss Programme

1.3.7.4 Summary

The literature review elucidated the health care system in the UK including weight management services. The prevalence of obesity in the UK has increased during the last two decades. Many studies included in this literature review have advocated rigorous weight-loss interventions such as nutrition counselling, physical activity, behavioural modification and social support. Also, previous studies have suggested that pharmacological treatment is an effective adjunct to dietary and lifestyle interventions in the treatment of obesity.

There are several options available to reduce weight, including reduced-energy diets, physical activity/exercise, behaviour modification, pharmacological intervention and surgery. One approach for overweight or obese adults to help manage weight loss is the participation in weight loss programmes. Many weight loss programmes provide strategies for the public to successfully achieve weight loss goals.

Treatments for obesity aim to help patients both lose and maintain weight loss. Many different health care providers may be involved in providing weight management services. Pharmacists provide both advice to obese customers on weight loss and structured programmes for them to follow. Pharmacotherapy, alongside a restricted calorie diet and increased exercise, is recommended a second line treatment for obesity by NICE.

BPWLP is not only a pharmacist-led weight management clinic but also where appropriate involves the supply of orlistat via a PGD to overweight or obese clients to help them lose weight. It consists of: 1) a consultation and assessment by a

pharmacist, 2) comprehensive support and advice on healthy eating and physical activity, 3) supply of a prescription only medicine (orlistat 120 mg, Xenical®) and 4) discount on Boots branded low calorie products and exercise equipment for Advantage card holders only. This programme is available to customers with a BMI equal to or greater than 30 kg/m^2 or 28 kg/m^2 with at least one co-morbidity related to risk factors.

As a result of the high prevalence of obesity, health commissioners are interested in determining which methods of weight loss programmes are more effective, whether they are CWLPs or NCWLPs. Although there is some evidence for NCWLPs, in the short- and long-term treatment of obesity, the evidence for commercial programmes is less clear and therefore this thesis considers CWLPs. The CWLP is an option for those overweight and obese patients who are willing and able to pay for such programmes. Thus, this thesis describes a systematic review of CWLPs to determine which factors are associated with successful programmes. Additionally, the thesis presents a before and after study of a CWLP delivered through pharmacies which determined the effectiveness of the programme.

1.4 Rationale for the study

Obesity and its resultant health problems have become an issue of global concern.[1] In the UK, obesity is a huge public health issue the incidence of which, in England, has tripled between 1980 and 2007 from around 7% to 24% of the general population.

Weight management services aim to reduce weight in individuals who are either overweight or obese. CWLPs can assist by not adding to NHS expenditure and also

by offering a variety of structured programmes where for-profit commercial organisations deliver weight loss interventions. Overweight and obese people who have participated in the CWLP have done so, in part, because they are willing and able to pay for such health benefits. A published study found that CWLPs were more effective than primary care based services in assisting clients to lose weight.[126] To offer supporting evidence of CWLPs, a systematic review was conducted, as one part of this thesis, to provide guidance for health care providers about successful programmes and their attributes.

Currently, there is only one available anti-obesity medicine; orlistat. In the UK orlistat was only available on prescription or via a PGD in pharmacist-led weight management clinics until 2009, when the 60 mg strength was licensed as a pharmacy medicine.

Studies of weight loss management services also have assessed the success of the programmes. Management through a combination of anti-obesity medicines with diet and exercise was significantly better than dietary regimens alone. However, with ever increasing numbers of obese people, a range of weight loss strategies may be necessary for the population, including preventative campaigns. Pharmacist-led weight management clinics, involving the supply of orlistat via PGD, have not been evaluated to determine whether or not they are effective in assisting people to lose weight and so the evaluation of one such service comprises the second part of this thesis.

Pharmacists contribute to weight management as a part of health promotion priorities.[111] The NHS and the Government White Paper potentially included community pharmacy as an ideal venue for weight loss programmes. There is little information about the reasons for clients participating in pharmacy-based weight loss programmes, how they attempted to control their weight in the past and their experiences of community pharmacy-based weight loss programmes. Therefore, to complement the evaluation of the effectiveness study a questionnaire was designed to explicit clients' views.

1.5 Aims and objectives

This study aimed to evaluate the effectiveness of commercial weight loss programmes in overweight and obese adults. The overall aims of this study were:

- To systematically review the effectiveness of commercial weight loss programmes in helping overweight and obese adults to lose weight.
- To evaluate the effectiveness of a pharmacist-led weight management clinic in achieving weight loss in obese clients through a combination of orlistat supply and advice.

1.5.1 Systematic review objectives

The objectives of the study were to:

- Systematically review the literature in order to describe the effectiveness of CWLPs in overweight and obese adults

- Determine whether there were particular characteristics of such programmes that indicated the success of CWLPs

1.5.2 Evaluation of Boots Pharmacy Weight Loss Programme objectives

1.5.2.1 Pilot study

The objectives of the pilot study were to:

- Test the data collection method and database
- Test the quality of the records in BPWLP
- Determine sample size calculation for the main study

1.5.2.2 Main study

The objectives of the main study were to:

- Describe the characteristics of clients who participated in the weight loss programme in terms of:
    - The length of time clients remained in the programme
    - The rate of unwanted effects based on the consultation notes
    - Reasons for dropout from the programme
- Determine the effect of the programme on body weight and BMI at three months
- Determine any associations between clients' biometric data at the initial visit and gender, age and length of time in the programme

- Determine characteristics associated with
    - Weight reduction at three months
    - Clients who achieved at least 5% weight loss

1.5.2.3 Questionnaire study

The survey study aimed to develop a questionnaire to determine the views of clients who participated in the BPWLP about the programme and other weight loss attempts.

Chapter 2

A systematic review of the effectiveness of commercial weight loss programmes

This chapter presents a systematic review of the effectiveness of commercial weight loss programmes (CWLPs) in helping overweight and obese adults to lose weight.

At the time of undertaking this current review, I was aware of only one previous systematic review of this subject, published in 2005 and containing only US studies.[116] However, this review did not provide information about the global, as opposed to national, effectiveness of CWLP and so an up-to-date systematic review covering the global literature sources was needed. Moreover, there is a lack of studies comparing weight management interventions within CWLPs in the UK. Many overweight and obese adults know little about the effectiveness of CWLPs[116] in their own countries. Therefore, this review will assist in identifying such successful weight management programmes.

2.1 Why this review matters

It has been reported that in the UK, the medical costs associated with obesity-related diseases will be £648 million each year by 2020 and £2 billion each year by 2030. By lowering the proportion of the UK population who are overweight or obese, the treatment costs associated with obesity-related diseases can be reduced.[127]

In the light of the rising prevalence of obesity, the need to find ways to assist people in losing weight has become increasingly important. Various weight management programmes and services offer to assist overweight and obese adults to lose weight. The programmes offered can be broadly divided into two groups, commercial weight loss programmes (CWLPs) and non-commercial weight loss programmes (NCWLPs). CWLPs are structured programmes which involve a for-profit commercial organisation delivering the weight loss intervention. These types of programmes are for those people who are willing and able to pay for the service. NCWLPs include organisations where weight loss interventions are offered free-of-charge, such as from government organisations, private health care provided as a part of health insurance, charities or social enterprises.

Very little is known about the effectiveness of CWLPs in facilitating weight loss in the many overweight and obese adults who take part in these programmes. The one previous systematic review on this subject was published in 2005 and only included US studies.[116]

2.2 Aim and objectives

The aim of this review was to assess the effectiveness of CWLPs in helping overweight and obese adults to lose weight.

The objectives of the review were to:

1. Describe the effectiveness of CWLPs in overweight and obese adults
2. Consider findings in the context of evidence published

2.3 Methods

2.3.1 The review team

The review team included the main (first) reviewer, Sukhumaphorn Sriwisit (SS); other reviewers included Helen Boardman (HB) and Anthony Avery (AA).

2.3.2 The review process

The review comprised five steps:[128] 1) framing the questions, 2) identifying relevant literature, 3) assessing the quality of the literature, 4) summarising the evidence (Results) and 5) interpreting the findings. A review protocol was developed to guide the review process.

2.3.2.1 Framing questions

The review question was framed in terms of the population (P), interventions (I) or comparators (C), outcomes of the studies (O) and study design (S).[129]

Population

The review used the WHO definition of 'overweight' as a Body Mass Index (BMI) ≥ 25 kg/m^2 and 'obesity' as a BMI ≥ 30 kg/m^2.[3] BMI is defined as the weight in kilograms divided by the square of the height in meters (kg/m^2). BMI provides the most useful population-level measure of the classifications of overweight and obesity for both genders and adults of all ages.

Intervention or comparison

A CWLP intervention was defined as a structured weight loss programme initiated by organisations delivering the intervention for profit, and where this is in the form of the provision of vouchers or partial subsidies. This review excluded NCWLP studies that, as stated in Chapter 1 (page 3), were offered free of charge to the user supported by government organisations, private health insurance, charities or social enterprises.

Outcome

The review included studies that collected, analysed and presented the effects of weight loss programmes on either weight or BMI.

Study design

The review incorporated interventions that used randomised controlled trials (RCTs) and randomised trials to assess intervention effect.

Defining these components allowed a framework to be developed for establishing the inclusion and exclusion criteria for studies included in the review. These preliminary inclusion and exclusion criteria are summarised in Table 2.1.

Table 2.1 Preliminary inclusion and exclusion criteria for identification of studies

Inclusion criteria	Exclusion criteria
Participants	
Participants aged 18 years or older Participants who were overweight and obese	Participants aged younger than 18 years
Intervention/comparison	
Commercial weight loss programmes	Non commercial weight loss programmes
Outcome	
Main outcomes: Changes in weight (kg or %) and/or BMI (kg/m^2 or %)	Main outcomes: Did not report weight and BMI changes
Study design	
Randomised controlled trials (RCTs), randomised trials, systematic reviews	Non-systematic reviews, controlled before and after study, before and after study or time series analysis
Published in the English language only	Not published in a language other than English
Published between 1 January 1980 and 31 December 2011	Published before January 1980 and after December 2011

2.3.2.2 Identifying relevant literature

Data sources

A multiple database search was used to identify studies for the review because one database cannot embrace all studies. Therefore, nine bibliographic databases were used to identify the literature for inclusion in the systematic review – see Table 2.2.

Table 2.2 A list of electronic databases searched for the systematic review

Database	Information provided	Searched for database
1. CENTRAL (The Cochrane Central Register of Controlled Trials, Clinical Trials)	Full text of regularly updated systematic reviews prepared by the Cochrane collaboration of completed reviews and protocols	Via The Cochrane Library
2. Medline (Medical Literature Analysis and Retrieval System Online)	Journal citations and abstracts for medicine, nursing, pharmacy, dentistry, psychiatry, veterinary and health care	Via OVID
3. EMBASE (Excerpta Medica Database)	The most comprehensive biomedical database on the internet, consisting of biomedical and pharmaceutical studies	Via OVID
4. CINAHL (Cumulative Index of Nursing and Allied health Literature)	The most comprehensive resource for nursing and allied health literature	Via EBSCO
5. IPA (International Pharmaceutical Abstracts)	Abstracts in clinical studies including study design, number of patients, dosage, dosage forms and dosage schedule	Via OVID
6. Scopus (SciVerse Scopus)	Abstracts and citations for academic peer-reviewed journal articles in the scientific, technical, medical and social sciences	Via SciVerse
7. WOS (Web of Science)	Multiple databases, cross-disciplinary research and in-depth exploration of specialized subfields within an academic or scientific discipline	Via Web of Knowledge
8. PsycINFO (Psychological Information Database)	Abstracts of literature in psychology and health care disciplines related	Via OVID
9. HMIC (Health Management Information Consortium)	Data related to health management and services, social care, service development or NHS organisation and administration	Via OVID

Search strategies

Search terms used were based on the four components of the review: 1) overweight or obese, 2) interventions: CWLP, 3) changes in weight or BMI and 4) study design. Searches were made using Medical Subject headings (MeSH), keywords or text words. Free text words which incorporated the use of wildcard truncations were used to help compile the search terms. Details of the terms used and how these were

combined were provided – see Appendix 2. The search strategy was tested and refined in order to try and achieve maximum sensitivity for obtaining relevant studies without generating an unmanageable number of references for review.

The criteria and process for excluding titles and abstracts, and including articles, is explained below. All stages of the process of selecting studies for this review were conducted by two reviewers (SS and HB). Any disagreements were resolved by discussion, if necessary involving a third reviewer (AA).

Defining criteria and the process of exclusion for titles

The titles of papers identified through the search were reviewed to eliminate those that were not relevant, using the terms of the following three components:

- Participants: The study did not include overweight or obese adults.
- Intervention: The study was not about weight loss.
- Study type: The study was not a systematic review, randomised trial or randomised controlled trial.

If there were insufficient details in the title, or the reviewer was unsure, the title was retained at this stage.

The process of reviewing the titles involved systematically selecting every 8th title, n = 1,060 (13%) to be reviewed by both reviewers. Ideally, at least 10% of samples are required to be checked.[130] However, sampling every 8th title was decided as a pragmatic number as that was approximately 1,000 titles. Following this, the titles included and excluded by both reviewers were compared. There was disagreement

on 48 (4.0%) of the titles. This was discussed and resulted in 19 titles being included and 29 titles excluded, based mainly on the reason that the research did not have weight loss as a primary outcome. The main reviewer (SS) analysed the remaining titles (n = 7,424), resulting in 772 titles being retained for inclusion in the process of abstract review (see flow diagram – Figure 2.2, page 72).

Exclusion criteria and process of exclusion of abstracts

After eliminating the article titles, the main reviewer (SS) applied the exclusion criteria to the remaining abstracts. The following exclusion criteria were used:

- Studies were excluded if they focused on the following groups of participants:
    - Normal weight or underweight adults
    - Aged younger than 18 years
    - Pregnant women or breast-feeding mothers
    - With an eating disorder or previous obesity surgery such as gastric banding, bariatric surgery or intragastric balloon
- Intervention: Studies were excluded if they were not about weight loss, weight change, weight reduction, weight control or weight management. In addition, studies focusing on the following interventions were excluded:
    - Non-commercial weight loss programmes funded by health care systems (government or public sector)
        - NHS, Medicaid, Medicare
        - Army or military
        - Hospitals both inpatients and outpatients
        - Primary care, general practice or health centre

  - Drugs withdrawn from the market such as Sibutramine (UK and Europe,[78] US[131] and Canada,[132] Australia[133] and New Zealand[134] markets) or Rimonabant (UK and Europe).[135] Disease specific diets e.g. for severe liver disease where the primary aim is not weight reduction

- Outcomes: Studies were excluded if the main outcome did not report weight loss, weight change or weight reduction (measured in kilograms or percentage change).
- Study type: Studies of the following types were excluded: qualitative studies, expert opinion, case studies, case series, case reports, symposium reports, non-systematic literature reviews, narrative reviews, comments, guidelines or questionnaire surveys.

As with reviewing titles, if there was insufficient detail in the abstract, or the reviewer was unsure, the papers were not excluded at this stage.

The process of reviewing the abstracts involved systematically selecting every 7th abstract, n = 110 (14%) to be reviewed by both reviewers. Ideally, at least 10% of samples are required to be checked.[130] However, sampling every 7th abstract was decided as a pragmatic number as this was approximately 100 abstracts. Following this, the abstracts included and excluded by both reviewers were compared. There was agreement on 100% of the abstracts. Two reviewers agreed on 51 (46.4%) papers to be included, and 59 (53.6%) papers to be excluded. Reasons of the 59 excluded titles were not having weight loss as a primary outcome (17), and criteria (28) and study type (14) for CWLPs. The main reviewer (SS) reviewed the remaining abstracts (n = 662). The total number of abstracts retained for the process

of a full article review was 153 (see flow diagram – Figure 2.2, page 72).

Inclusion and exclusion criteria and process of selecting full articles

After eliminating certain papers by reviewing their abstracts, the inclusion and exclusion criteria for full articles were applied to the remaining articles. The inclusion and exclusion criteria, shown in Table 2.3 were used.

Table 2.3 The criteria of inclusion and exclusion for full articles

Characteristics of the study	Inclusion criteria	Exclusion criteria
Participants	At least 80% of the participants in this study were: - Overweight adults as having BMI $\geq$ 25 kg/m^2 or $\geq$ 22 kg/m^2 in Asian people - Obese adults as having BMI $\geq$ 30 kg/m^2 or $\geq$ 25 kg/m^2 in Asian people	Participants were younger than 18 years old.
Interventions		
Nature of interventions	Commercial weight loss programme (CWLP)	The only difference between intervention and control is a product or supplement.
Organisation	- A structured programme - Organisation delivering the intervention is for a profit commercial organisation and in the form of the provision of vouchers or partial subsidies	- Government organisation - Private health care provided as a part of health insurance - Charity - Social enterprise
Duration of programme	4 weeks and longer	Less than 4 weeks
Outcomes	Primary outcome was weight loss or weight change expressed as: - Mass change - BMI change - Percentage change	The main outcome did not report weight loss, weight change or weight reduction
Study types	- Randomised controlled trial - Randomised trial - Controlled trial - Time series analysis	- Conference abstract - Study protocol - Commentary - Before and after study - Systematic review

The process of reviewing all full articles (n = 153) involved both reviewers using a checklist form – see Figure 2.1. Following this, all full articles included and excluded by both reviewers were compared. The reviewers agreed 100% with the 21 (14%) articles to be included and 132 (86%) articles to be excluded. Reasons for exclusion and results for full articles excluded were shown in Figure 2.2, page 72. There were 21 full articles retained for the data extraction and quality assessment.

Article identification:	Reviewer's initials:	
Author and year:	Country:	
	Met the criteria for	
	Inclusion	Exclusion
Participants: At least 80% of the participants in this study were		
Overweight adults as having BMI ≥ 25 kg/m^2 or ≥ 22 kg/m^2 in Asian people	☐	☐
Obese adults as having BMI ≥ 30 kg/m^2 or ≥ 25 kg/m^2 in Asian people	☐	☐
Interventions		
Nature of intervention		
1. Commercial weight loss programme	☐	X
2. The only difference between intervention and control is a product.	X	☐
Organization		
1. A structured programme	☐	X
2. Organization delivering the intervention is a 'for profit' commercial organization	☐	X
3. Government organization	X	☐
4. Private health care company and the programme is provided as a part of health insurance	X	☐
5. Charity	X	☐
6. Social enterprise	X	☐
Duration of programme		
If ≥ 4 weeks	☐	X
If < 4 weeks	X	☐
Outcomes: If primary outcome was weight change expressed as		
Mass (weight) change	☐	X
Percentage change in weight	☐	X
BMI change	☐	X
Percentage BMI change	☐	X
Study types		
Randomized controlled trial ☐ Controlled trials ☐		
Before and after study ☐ Time series analysis ☐	☐	☐
Systematic reviews ☐ Ineligible study ……. ☐		
Initial decision	☐	☐
Final agreed decision between reviewers	☐	☐
Comments:		

Figure 2.1 A check list form for inclusion and exclusion of full articles

2.3.2.3 Data extraction and assessing quality of literature

Data extraction

All relevant data were extracted from the full articles which met the inclusion criteria. A data extraction form was developed by SS – see Appendix 3. This data extraction form was adapted from the Cochrane reviews by Higgins and Green,[136] CONSORT (Consolidated Standards of Reporting Trials) statement of randomised trials of non-pharmacological treatment[137] and systematic reviews by Khan et al.[128] The data was then summarised into data extraction tables by SS. These summaries were checked by the second reviewer (HB) for accuracy. Any disagreement or queries arising from data extraction were discussed among the team, and information was clarified and/or corrected accordingly.

CONSORT is a checklist for reporting randomised controlled trials (RCTs) which may also be used for reviewing of RCTs.[138] CONSORT defines standards for RCTs to ensure quality in reporting and covers area such as randomisation, blinding and generalisability. The purpose of CONSORT in this review was to aid data extraction and to provide a clear and consistent description from the randomised trials.[128] All variables on the CONSORT checklist were extracted from the studies where possible. In addition, the source of funding was added to the data extraction form (Appendix 3).

Quality assessment

Studies within this review may contain reporting bias, which can result where the authors report their study in such a way that it overestimates the effect of the intervention.[128, 136] Bias may result from inadequacies in the study design (such as the

flaws in allocation concealment), outcome assessment or use of statistical methods.[139] It was not possible to determine to what extent bias affected the methods (internal validity) and results of the studies; however the risk of bias is acknowledged as a potential influence in this review. In order to assess bias consistency for all studies a risk of bias tool was used[136] – see Appendix 4.

In this review, the purpose of the risk of bias tool was to assist in describing heterogeneity (methodological diversity such as differences among studies in terms of allocation concealment and blinding) in the design and results of the included studies.[136] For the design of the included studies, blinding was not always possible to achieve for the weight loss interventions because participants would be aware of their diet and any exercise taken. Whilst blinding would normally be a desirable characteristic of a RCT, it was felt inappropriate to judge weight loss interventions that did not incorporate blinding as being interventions of a low quality because of the difficulty in achieving blinding. However, this does not mean that such interventions were un-biased.[136]

Using risk of bias is preferable in assessing quality as this tool does not use quality scales to yield a summary score. The use of quality scales can be unreliable as they have been designed for specific types of trials and are not always suitable for other trial types. For example, two widely used tools for assessing quality are the Jadad scoring system[140] and Evidence-based behavioural medicine system (EBBM).[141] The Jadad scoring system[140] does not include a score related to allocation concealment which is one of the most important potential biases in randomised trials.[136] This tool also gives a high weighting to blinding which is rarely possible in diet and exercise

trials. EBBM[141] tool focuses on behavioural interventions assessing training, supervision, preference and manner of treatment providers including treatment adherence. In this systematic review the effectiveness of the intervention was the primary outcome and therefore the EBBM tool would not assess the relevant areas for the study. Therefore, the risk of bias is the most suitable tool to assess the quality of the studies for this review.

The risk of bias tool comprises a description and a judgement on the standard risk of bias by reviewing intervention components such as sequence generation, allocation sequence concealment, blinding, incomplete outcome data, selective outcome reporting and other potential sources of bias – see Table 2.4.[136, 142] This assessment tool provides a brief free text description or summary of the relevant trial characteristics and involves assigning a judgement of high, low or unclear risk for each item. For example, where a positive response to a question indicated a suitable procedure to minimise bias (e.g. whether or not the allocation was adequately concealed) this was translated into a low risk of bias. On the other hand, where a negative response to a question indicated a lack of an unsuitable procedure to maximise bias, this was translated into a high risk of bias.

The risk of bias of each study was assessed by SS and checked by a second reviewer (HB). In comparing the two assessors' judgements of the risk of bias, any disagreements were resolved by discussion, if necessary involving AA. There was disagreement on eight articles in a domain of random sequence generation. This was discussed and informed to AA with the result that a low risk of bias in a domain of random sequence generation has been changed to an unclear risk of bias.

Table 2.4 Classification scheme for bias assessment

Type of bias	Source of bias	Support for judgement	Review authors' judgement
Selection bias	Sequence generation	Describe the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups	Was the allocation sequence adequately generated?
	Allocation concealment	Describe the method used to conceal the allocation sequence in sufficient detail to determine whether intervention allocations could have been foreseen before or during enrolment	Was allocation adequately concealed?
Performance bias	Blinding of participants and personnel*	Describe all measures used. If any, to blind trial participants and researchers from knowledge of which intervention a participant received. Provide any information relating to whether the intended blinding was effective	Was knowledge of the allocated intervention adequately prevented during the study?
Detection bias	Blinding of outcome assessment**	Describe all measures used. If any, to blind outcome assessment from knowledge of which intervention a participant received. Provide any information relating to whether the intended blinding was effective	Was knowledge of the allocated intervention adequately prevented during the study?
Attrition bias	Incomplete outcome data	Describe the completeness of outcome data for each main outcome including attrition and exclusions from the analysis. State whether attrition and exclusions were reported, the numbers in each intervention group (compared with total randomised participants), reasons for attrition or exclusions where reported, any reinclusions in analysis for the review	Were incomplete outcome data adequately addressed?
Reporting bias	Selective reporting	State how selective outcome reporting was examined an what was found	Are reports of the study free of suggestion of selective outcome reporting?
Other bias	Anything else, ideally prespecified	State any important concerns about bias not covered in the other domains in the tool	Was the study apparently free of other problems that could put it at a high risk of bias?

*In reality it is very hard to blind participants in this type of trials as they will know what they are eating and how much exercise they take. However the data collection can be blinded to the trial arm and therefore we considered blinding in the assessment of the risk of bias. **Assessments should be made for each main outcome or class of outcomes.

2.3.2.4 Data synthesis

Data synthesis was used to conduct a narrative review, with tabulation of results, for all studies included. Information about each of the three main intervention components of diet; diet and exercise; and meal replacement were discussed as described below:

1. Diet:[143] where a reduced-energy diet was the primary focus of the intervention, along with behavioural modification with or without a peer or group support or verbal or written advice on how to lose weight or participation in group meetings. This intervention also included very low calorie diets[143] which typically are less than 800 kcal per day, commonly in a form of a liquid diet and used as the initial weight loss intervention.
2. Diet and exercise:[143] a reduced-energy diet along with behavioural modification, with a recommended-specific goal for physical activity and with a peer or group support or with verbal or written advice on how to lose weight or participation in group meetings.
3. Meal replacement:[143] having two or more replacement meals per day as an adjunct to a reduced-energy diet with or without a peer or group support or a given verbal or written counselling on how to lose weight or participate in a meeting session

The effectiveness of CWLPs was assessed by comparing results from the pooled data and the different comparator groups. The studies were not combined in a meta-analysis due to differences in the interventions, comparators and populations in all studies included.

2.4 Results

2.4.1 Summary of the evidence

2.4.1.1 Studies retrieved

16,356 citations were obtained from the initial database search, from which 153 full articles were obtained for further scrutiny. From these, 132 articles were rejected leaving 21 articles to be retained for inclusion in the review. However, one study reported the same data as a previous study so that the final total was of 20 studies to be included in this review – see Figure 2.2.

Regarding the excluded articles, reasons for exclusion are shown in Figure 2.2. Focus on a non-commercial weight loss programme was the main reason for exclusion of full articles (n = 81, 61%). Other reasons for exclusion include study type (systematic review or before and after study) and entry criteria for BMI not being stated.

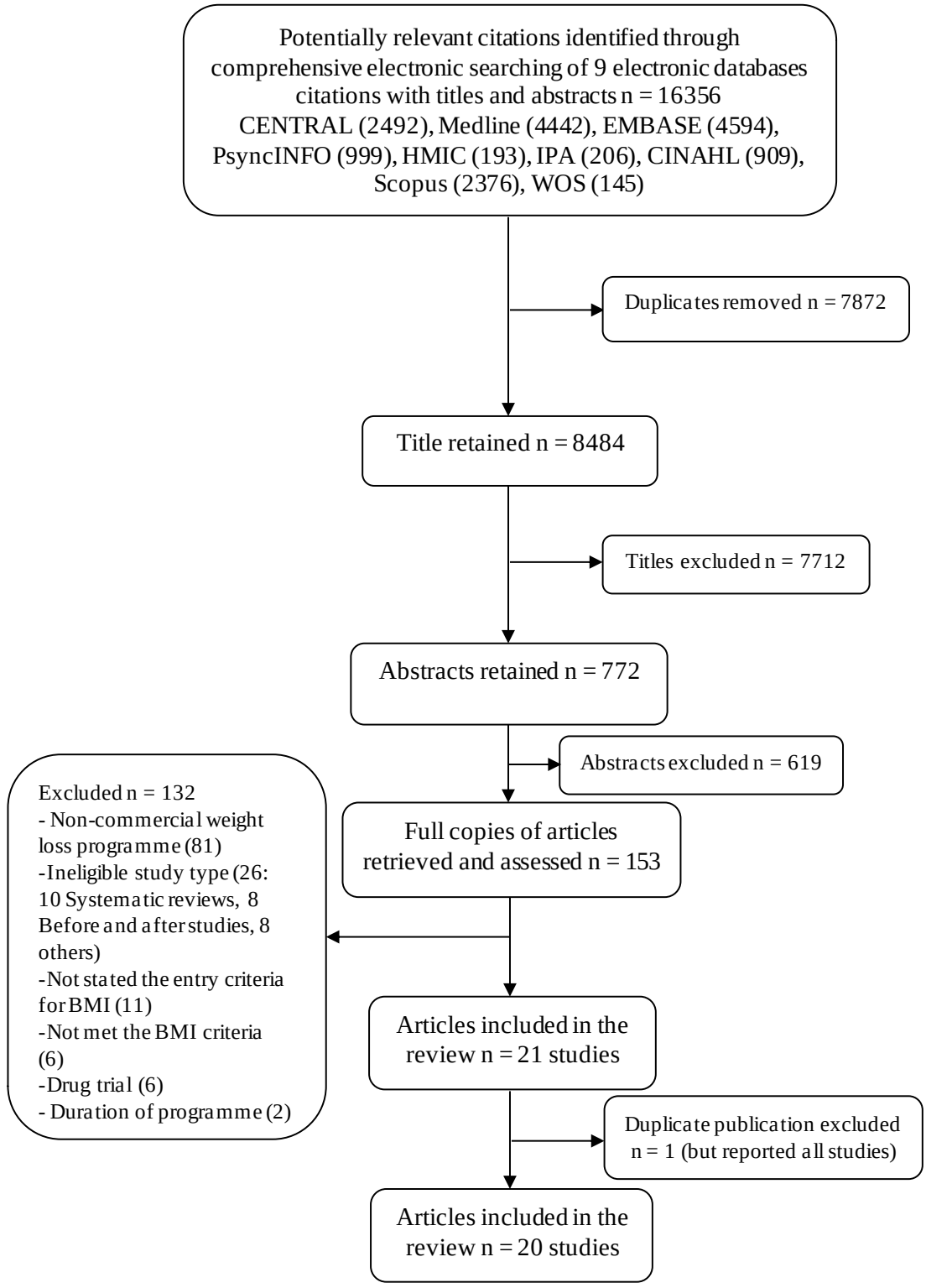

Figure 2.2 Study identification process

2.4.1.2 Summary of studies reviewed

The 20 studies in the final review involved a combined total of 5,522 overweight or obese adult participants. Seventy percent of studies (14/20)[11, 113, 117, 119, 144-155] were conducted in the US – see Table 2.5.

Table 2.5 Studies included in the review

First author	Year	Country	Outcomes
Anderson[144]	2011	US	Weight loss
Dansinger[11]	2005	US	Weight change
Djuric[145]	2002	US	Weight loss
Donnelly[146]	2007	US	Weight loss
Foster[147]	2009	US	Weight and BMI changes
Gardner[117]	2007	US	Weight loss
Gold[148]	2007	US	Weight change
Green[149]	2005	UK, US	Weight loss
Haapala[124]	2009	Finland	Weight change
Heshka[150, 151]	2000 and 2003	US	Weight and BMI changes
Jebb[152]	2011	US	Weight loss
Jolly[17]	2011	UK	Weight loss
Luszczynska[156]	2007	UK, Poland	Weight and BMI changes
Rock[153]	2007	US	Weight loss
Rock[154]	2010	US	Weight loss
Rolland[119]	2009	US	Weight loss
Shuger[155]	2011	US	Weight and BMI changes
Truby[126]	2006	UK	Weight change
Van Wier[157]	2011	Netherlands	Weight loss
Womble[113]	2004	US	Weight change

Seventeen (85%) of the studies included both men and women participants. three (15%) studies only had women participants. The mean age in the majority of studies (70%) was between 40 and 50 years. The mean age of participants was younger than 40 years in one study and over 50 years in another. There were four studies that did not report mean age at baseline – see Table 2.6.

Thirteen (65%) studies had participants with a mean BMI at baseline in obesity class I, five studies (25%) had those in obesity class II and the last two (10%) studies had a mean BMI indicating overweight participants – see Table 2.6.

Table 2.6 Participants' characteristics of studies included in the review

Criterion	Category	Number	Studies (First author)
Gender	Both men and women	17	Anderson,[144] Dansinger,[11] Djuric,[145] Donnelly,[146] Foster,[147] Gold,[148] Green,[149] Haapala,[124] Heshka,[150] Jebb,[152] Jolly,[17] Luszczynska,[156] Rolland,[119] Shuger,[155] Truby,[126] Van Wier,[157] Womble[113]
	Only women	3	Gardner,[117] Rock[153] and Rock[154]
Mean age at baseline	< 40 years	1	Haapala[124]
	40-49.9 years	14	Anderson,[144] Dansinger,[11] Gardner,[117] Gold,[148] Heshka,[150] Jebb,[152] Jolly,[17] Rock,[153, 154] Rolland,[119] Shuger,[155] Truby,[126] Van Wier,[157] Womble[113]
	50 years and older	1	Foster[147]
	Mean age not reported	4	Luszczynska,[156] Donnelly,[146] Green,[149] Djuric[145]
Mean BMI at baseline	25-29.9 kg/m^2	2	Green,[149] Van Wier[157]
	30-34.9 kg/m^2	13	Donnelly,[146] Gardner,[117] Gold,[148] Haapala,[124] Heshka,[150] Jebb,[152] Jolly,[17] Luszczynska,[156] Rock,[153] Rock,[154] Shuger,[155] Truby,[126] Womble[113]
	35-39.9 kg/m^2	5	Anderson,[144] Dansinger,[11] Djuric,[145] Foster,[147] Rolland[119]

2.4.1.3 Study design

Most of the studies took place in a primary care or community-based setting, with about a quarter of the studies (n = 5)[119, 126, 146, 150, 151] being conducted in settings such as a weight management clinics or Weight Watchers clinics – see Table 2.7. In 15 (75%) studies, participants were involved in the weight loss programme for over three months, whilst those in the remaining studies (25%) participated for up to three months.

Recruitment methods for almost half of the studies were media advertisements. Seven (35%) studies recruited participants by mail and others included website programmes (e-mail distributors), interviews, obesity clinics, community events, worksites, press releases or brochures. Four (20%) studies recruited participants from referrals by health care providers, whilst the remaining studies recruited patients by selecting from records of participants already attending the programme and sending out a questionnaire.

Table 2.7 Characteristics of studies included in the review (n = 21)

Criterion	Category	Number	Studies (First author)
Setting	Primary care	4	Anderson,[144] Dansinger,[11] Jebb,[152] Jolly[17]
	Secondary care	4	Djuric,[145] Haapala,[124] Heshka,[150] Rolland[119]
	Community setting (Not health care)	4	Green,[149] Gardner,[117] Shuger,[155] Truby[126]
	Work place	2	Van Wier,[157] Womble[113]
	Not clear	1	Foster[147]
	Others, including weight management clinics and Weight Watchers clinics	5	Donnelly,[146] Gold,[148] Luszczynska,[156] Rock[153, 154]
Length of treatment	More than 3 months	15	Anderson,[144] Dansinger,[11] Djuric,[145] Gardner,[117] Gold,[148] Haapala,[124] Heshka,[150] Jebb,[152] Rock,[153] Rock,[154] Rolland,[119] Shuger,[155] Truby,[126] Van Wier,[157] Womble[113]
	Up to 3 months	5	Donnelly,[146] Foster,[147] Green,[149] Jolly,[17] Luszczynska[156]
Recruitment*	Media advertisements	9	Anderson,[144] Dansinger,[11] Foster,[147] Gardner,[117] Green,[149] Haapala,[124] Rock,[154] Shuger,[155] Truby[126]
	Mailing and others	7	Djuric,[145] Donnelly,[146] Gold,[148] Haapala,[124] Rock,[153] Van Wier,[157] Womble[113]
	Referred by health care providers	4	Foster,[147] Jebb,[152] Jolly,[17] Rolland[119]
	Selected from records	1	Heshka[150]
	Already attending	1	Luszczynska[156]

*Many studies had more than one method of recruitment.

2.4.1.4 Intervention

The majority (80%) of interventions delivered compared CWLPs involving diet and exercise. The remaining studies were focussed on diet and meal replacement. Three key elements in all diet groups are restriction on calorie level (total kcal/day), exercise (daily or optional) and support (description of support) – see Table 2.8.

Thirteen studies were supported by health care providers including dieticians, counsellors, doctors, therapists, nurses, food advisors, group support, trained workers and facilitators. Group support was evident in 11 studies. Internet and telephone support was found in eight and seven studies, respectively, whilst external support, in the form of a book, was provided in two studies.

The main outcome reported was weight loss in 11 (55%) studies and weight change in six (30%) studies. Only three (15%) studies presented both weight and BMI changes as main outcomes. Four (20%) studies reported adverse events whilst the remainder did not report adverse events.

There was a total of 46 interventions in the 20 studies. Most groups had dropout rates of between 11% and 49% for either intervention or control groups. Three studies had a dropout rate higher than 50% for the intervention group, whilst none of the studies had a high dropout rate for the control group.

Table 2.8 Components of interventions in studies included in the review (n = 21)

Criterion	Category	Number	Studies (First author)
Intervention delivery	Diet and exercise	16	Dansinger,[11] Djuric,[145] Foster,[147] Gardner,[117] Gold,[148] Haapala,[124] Heshka,[150] Jebb,[152] Jolly,[17] Luszczynska,[156] Rock,[153] Rock,[154] Shuger,[155] Truby,[126] Van Wier,[157] Womble[113]
	Diet	2	Green,[149] Rolland[119]
	Meal replacement	2	Anderson,[144] Donnelly[146]
Support*	All providers	13	Anderson,[144] Djuric,[145] Donnelly,[146] Foster,[147] Gardner,[117] Jolly,[17] Rock,[153] Rock,[154] Rolland,[119] Shuger,[155] Truby,[126] Van Wier,[157] Womble[113]
	Group	11	Foster,[147] Gardner,[117] Gold,[148] Green,[149] Heshka,[150] Jebb,[152] Jolly,[17] Luszczynska,[156] Rolland,[119] Truby,[126] Womble[113]
	Internet	8	Gold,[148] Haapala,[124] Jolly,[17] Rock,[153] Rock,[154] Rolland,[119] Van Wier,[157] Womble[113]
	Telephone	7	Djuric,[145] Haapala,[124] Jolly,[17] Rock,[153] Rock,[154] Rolland,[119] Shuger,[155] Van Wier[157]
	External (book)	2	Dansinger,[11] Truby[126]
	No support (control group)	2	Djuric,[145] Truby[126]
Outcomes	Weight loss	11	Anderson,[144] Djuric,[145] Donnelly,[146] Gardner,[117] Green,[149] Jebb,[152] Jolly,[17] Rock,[153] Rock,[154] Rolland,[119] Van Wier[157]
	Weight change	6	Dansinger,[11] Foster,[147] Gold,[148] Haapala,[124] Truby,[126] Womble[113]
	Weight and BMI changes	3	Heshka,[150] Luszczynska,[156] Shuger[155]
Adverse events	Report	4	Anderson,[144] Dansinger,[11] Heshka,[150] Jebb[152]
	Did not report	16	Djuric,[145] Donnelly,[146] Foster,[147] Gardner,[117] Gold,[148] Green,[149] Haapala,[124] Jolly,[17] Luszczynska,[156] Rock,[153] Rock,[154] Rolland,[119] Shuger[155] Truby,[126] Van Wier,[157] Womble[113]

*Many studies had more than one method of support.

Table 2.8 (continued)

Criterion	Category	Number	Studies (First author)
Dropout rate			
Intervention**	≥ 50%	4	Dansinger,[11] Djuric,[145] Rolland,[119] Jolly[17]
	11-49%	36	Anderson,[144] Donnelly,[146] Gardner,[117] Gold,[148] Haapala,[124] Heshka,[150] Jebb,[152] Jolly,[17] Rock,[154] Truby,[126] Van Wier,[157] Womble[113]
	≤ 10%	4	Foster,[147] Haapala,[124] Rock,[153] Shuger[155]
	Did not report	2	Green,[149] Luszczynska[156]
Control	≥ 50%	-	-
	11-49%	37	Anderson,[144] Dansinger,[11] Djuric,[145] Donnelly,[146] Gardner,[117] Gold,[148] Haapala,[124] Heshka,[150] Jebb,[152] Shuger,[155]Truby,[126] Van Wier,[157] Womble[113]
	≤ 10%	3	Foster,[147] Rock,[153] Rock[154]
	Did not report	4	Djuric,[145] Green,[149] Jolly,[17] Luszczynska[156]

**Many studies had more than one intervention.

2.4.2 Quality assessment of the studies

The risk of bias was assessed for a study across outcomes (each of the seven methodological criteria), an outcome within a study (across domains) and a review as a whole.

2.4.2.1 Risk of bias for a study across outcomes

Risk of bias for studies across outcomes was summarised by the total number of key domains for each study, each of the seven domains represents a different risk of bias. Low risk of bias suggests a plausible bias is unlikely to seriously alter the results; unclear risk of bias raises some doubt about the results. High risk of bias is perceived bias that seriously weakens confidence in the results.

A lack of blinding of participants and personnel was the main area where many studies (n = 19, 90.5%) had a high risk of bias. Blinding of the outcome assessment and allocation concealment had the highest number of studies where the bias was unclear. Other bias and random sequence generation were where most studies had a low risk of bias – see Table 2.9.

Table 2.9 Summary assessments of the risk of bias for all domains across studies (n = 21)

Key domains across studies	Risk of bias, number of studies and studies (First author)		
	Low	Unclear	High
Random sequence generation	13	8	-
	Anderson,[144] Dansinger,[11] Foster,[147] Gardner,[117] Heshka,[150, 151] Jebb,[152] Jolly,[17] Luszczynska,[156] Rock,[154] Shuger,[155] Truby,[126] Van Wier[157]	Djuric,[145] Donnelly,[146] Gold,[148] Green,[149] Haapala,[124] Rock,[153] Rolland,[119] Womble[113]	-
Allocation concealment	7	14	-
	Gardner,[117] Haapala,[124] Heshka,[150, 151] Jebb,[152] Jolly,[17] Van Wier[157]	Anderson,[144] Dansinger,[11] Djuric,[145] Donnelly,[146] Foster,[147] Gold,[148] Green,[149] Luszczynska,[156] Rock,[153, 154] Rolland,[119] Shuger,[155] Truby,[126] Womble[113]	-
Blinding of participants and personnel	2	-	19
	Heshka,[150] Luszczynska[156]	-	Anderson,[144] Dansinger,[11] Djuric,[145] Donnelly,[146] Foster,[147] Gardner,[117] Gold,[148] Green,[149] Haapala,[124] Heshka,[151] Jebb,[152] Jolly,[17] Rock,[153, 154] Rolland,[119] Shuger,[155] Truby,[126] Van Wier,[157] Womble[113]

Table 2.9 (continued)

Key domains across studies	Risk of bias, number of studies and studies (First author)		
	Low	Unclear	High
Blinding of outcome assessment	4	15	2
	Dansinger,[11] Gardner,[117] Heshka,[150] Luszczynska[156]	Anderson,[144] Djuric,[145] Donnelly,[146] Foster,[147] Gardner,[117] Gold,[148] Green,[149] Haapala,[124] Heshka,[151] Jebb,[152] Rock,[153] Rolland,[119] Shuger,[155] Truby,[126] Van Wier,[157] Womble[113]	Jolly,[17] Rock[154]
Incomplete outcome data	12	5	4
	Gardner,[117] Gold,[148] Foster,[147] Heshka,[150, 151] Jebb,[152] Rock,[153, 154] Shuger,[155] Truby,[126] Van Wier,[157] Womble[113]	Djuric,[145] Donnelly,[146] Jolly,[17] Luszczynska,[156] Rolland[119]	Anderson,[144] Dansinger,[11] Green,[149] Haapala[124]
Selective reporting	19	-	2
	Anderson,[144] Dansinger,[11] Djuric,[145] Foster,[147] Gardner,[117] Gold,[148] Haapala,[124] Heshka,[150, 151] Jebb,[152] Jolly,[17] Luszczynska,[156] Rock,[153, 154] Rolland,[119] Shuger,[155] Truby,[126] Van Wier,[157] Womble[113]	-	Donnelly,[146] Green[149]
Other bias	19	-	2
	Anderson,[144] Dansinger,[11] Djuric,[145] Foster,[147] Gardner,[117] Gold,[148] Haapala,[124] Heshka,[150, 151] Jebb,[152] Jolly,[17] Luszczynska,[156] Rock,[153, 154] Rolland,[119] Shuger,[155] Truby,[126] Van Wier,[157] Womble[113]	-	Donnelly,[146] Green[149]

2.4.2.2 Risk of bias for the review as a whole

Risk of bias for this review as a whole was summarised by the percentage of risk of bias across both studies and domains. Over 90% of studies were at a low risk of bias for selective reporting and other bias, whilst 90% of studies were approximately at high risk of bias for blinding of participants and personnel. Over 70% of studies were at an unclear risk of bias for blinding of outcome assessment whilst 50% of studies were approximately at low risk of bias for incomplete outcome data. For selection bias, 62% and 38% of studies were at low and unclear risk of bias respectively for random sequence generation whilst 33% and 67% of studies were approximately at low and unclear risk of bias for allocation concealment, respectively – see Figure 2.3.

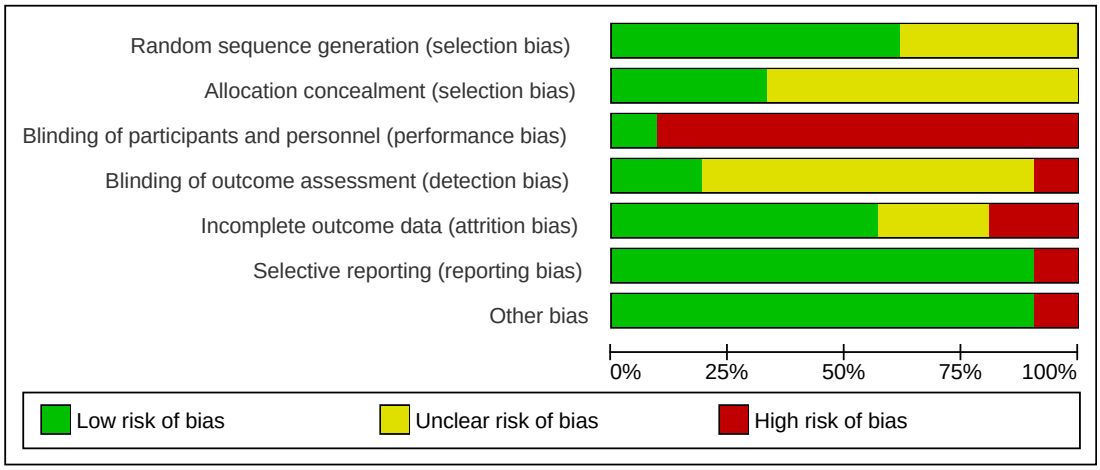

Figure 2.3 Risk of bias graph for all included studies

2.4.2.3 Risk of bias across domains

Risk of bias across domains within each study shows variation in the quality of studies. Heshka and colleagues[150] study was at low risk of bias for all domains unlike Green[149] and Donnelly[146] whose studies had no domains at low risk of bias. Two studies[150, 156] had no domains at high risk of bias whereas two studies[146, 149] had three or four domains at high risk of bias – see Figure 2.4.

Figure 2.4 Risk of bias summary of all included studies

The appraisal of methodological quality did not allow for all 21 randomised trials to be considered "best" or "worst" in terms of risk of bias. However this review was able to separately assess the low risk of bias. Studies were assessed as 'an unclear risk of bias' when too few details were available to make a judgement of a high or low risk of bias. However, most studies have combined the unclear and high domains.[136] These will report that the average bias in results will reveal fewer studies at a high risk of bias. This current review found that 17 (81%)[11, 17, 113, 117, 124, 126, 144, 147, 148, 150-157] studies were associated with a low risk of bias, whilst the remaining studies were associated with an unclear (n = 3, 14%)[119, 145, 146] and high (n = 1, 5%)[149] risk of bias, respectively.

2.4.2.4 Reporting of strengths and limitations in the studies

Strengths

There were reports of strengths in three studies of Gold and colleagues,[148] Jolly and colleagues[17] and Van Wier and colleagues.[157]

The strengths of the Gold and colleagues[148] study was that it was the first study to investigate a commercial online weight loss programme without additional professional contact compared with a traditional face-to-face programme. Subjects who were involved with the online structured behaviour weight loss website could achieve their weight loss.

Jolly and colleagues[17] reported their study was a robust evaluation of commercial weight loss services which included a diversity of ethnic groups and tested people's willingness to pay to participate in such programmes, whilst Van Wier and

colleagues[157] reported using a theory-based intervention in a Dutch occupational setting.

Limitations

There were similar limitations in several studies. More than half of the studies had limitations in terms of a small sample size. The remaining limitations were principally around them being a short-term treatment, unknown effects of self-reporting, low recruitment rates and high loss to follow-up. Three studies did not report limitations – see Table 2.10.

Table 2.10 Summary of limitation of studies included in the review

Limitations	Number	Studies (First author)
Small sample size	11	Anderson,[144] Dansinger,[11] Foster,[147] Gardner,[117] Green,[149] Haapala,[124] Luszczynska,[156] Rock,[153] Rolland,[119] Truby,[126] Womble[113]
Short term study	8	Foster,[147] Green,[149] Haapala,[124] Heshka,[150, 151] Jebb,[152] Jolly,[17] Rolland,[119] Shuger[155]
Others		
- Unknown effects from self-reporting	2	Donnelly,[146] Jolly[17]
- Low recruitment rates	1	Jolly[17]
- Loss to follow-up	1	Van Wier[157]
No limitations reported	31	Djuric,[145] Gold,[148] Truby[126]

2.4.3 Description of included studies and their findings

The 20 studies were categorised by three main intervention components. Sixteen studies consisted of diet and exercise programmes[11, 17, 113, 117, 124, 126, 145, 147, 148, 150-157] whilst two studies each focussed on diet[119, 149] and meal replacement.[144, 146] All

studies are described in Appendix 5 that follows the full information by alphabetical study.

2.4.3.1 Diet

There were two RCTs for where the main intervention was diet. Lengths of the studies were eight weeks[149] and nine months[119] – see Table 2.11.

Green and colleagues[149] investigated whether the dieting were related to cortico-steroid secretion in the early stages of weight loss, by comparing three groups which consisted of supported and unsupported dieters, and a control group. They found that participants' mean weight losses in the supported and unsupported dieters, and control were -2.65 kg (-3.3%), -2.16 kg (-2.9%) and -0.05 kg (-0.007%) respectively, however there was no significant difference between the three groups.

Rolland and colleagues[119] evaluated the effectiveness of a low-carbohydrate/high-protein diet (LCHP), a commercial very low-calorie diet (VLCD) or LighterLife programme (LL), and a 600 kcal-deficient (CDD) diet in an obese population. Participants' weight loss in LL was higher than that in LCHP, -11.6 kg (-9.5%) vs -2.8 kg (-2.5%) at 3 months, -15.1 kg (-12.3%) vs -2.0 kg (-1.8%) at 9 months, p = 0.007.

Table 2.11 Study details of interventions for diet

Study	Participants	Interventions	Weight or BMI changes
Green et al.[149] 2005, UK, US N = 55 RCT	Settings: Community in Birmingham, UK Age 20-45 years, BMI 25-29 kg/m^2 Both women and men Mean weight 76.54 kg Mean BMI 28.1 kg/m^2	Completers: 16 participants in control group 25 participants - unsupported dieters 14 participants - supported dieters Duration: 8 weeks	Control:* -0.05 ± 2.84 kg (-0.07%) Unsupported dieters:* -2.16 ± 7.24 kg (-2.9%) Supported dieters:* -2.65 ± 3.28 kg (-3.3%) NS**
Rolland et al.[119] 2009, UK N = 72 Randomised controlled clinical trial	Settings: Specialist Obesity Clinic Age older than 18, BMI ≥ 35 kg/m^2 61 women, 11 men Mean age 42.7 years Mean weight 117.1 kg Mean BMI 39.9 kg/m^2	34 patients in LighterLife (LL) 38 patients in low-carbohydrate/high-protein diet (LCHP) Duration: 9 months	At 3 and 9 months weight loss, LL: -11.6 ± 12.9 kg (-9.5%) and -15.1 ± 21.1 kg (-12.3%), respectively LCHP: -2.8 ± 4.5 kg (-2.5%) and -2.0 ± 5.0 kg (-1.8%), respectively *p*-value = 0.007

*mean ± SE, **No significant difference

2.4.3.2 Diet and exercise

There were 16 RCTs for diet and exercise, with or without support, with the length of treatment varied from 12 weeks to 24 months – see Table 2.12.

Dansinger and colleagues[11] examined the effectiveness of four popular diets – Atkins, Zone, Weight Watchers (WW) and Ornish – on weight loss. At one year, overweight or obese participants' mean weight losses with Atkins (-2.1 kg, -2.1%), Zone (-3.2 kg, -3.2%), WW (-3.0 kg, -3.0%) and Ornish (-3.3 kg, -3.2%) indicated statistically significant differences within groups ($p < 0.01$). However, there was no statistically significant difference between groups ($p = 0.40$).

Djuric and colleagues[145] assessed the effects of combining weight-loss counselling with the WW plan on weight loss for obese women with breast cancer. The weight loss in participants receiving the individualised counselling and attending WW weekly meetings was highest at 12 months, -9.4 kg. There was a significant difference from the control group (-0.85 kg), $p < 0.05$.

Foster and colleagues[147] evaluated the effects of two CWLPs on weight and glycemic control among obese patients with type 2 diabetes. The first involved a prepackaged, portion-controlled diet plan (PCD: NutriSystem® DTM PCD) and the second a diabetes support and education (DSE) programme. At three months, participants' weight loss with the NutriSystem® DTM PCD programme was -8.2 kg (95% CI: 9.5 to -6.7, -7.1%) compared with -0.6 kg (95% CI: -2.0 to 0.8, -0.4%), $p < 0.0001$. For mean BMI at three months, PCD and DSE were -2.6 kg/m^2 and -0.4 kg/m^2, $p < 0.0001$.

Gardner and colleagues[117] examined the effects of four weight loss diets ranging from low to high carbohydrate intake on weight loss among overweight and obese pre-menopausal women. At 12 months, the Atkins group (-4.7 kg, -5.5%) resulted in greater weight loss than the other three groups which were LEARN (-2.2 kg, -2.6%), Ornish (-2.6 kg, -1.9%) and Zone (-1.6 kg, -1.9%). Comparing Atkins and Zone diets showed in a statistically significant difference ($p = 0.01$). However, there were no statistically significant differences among Zone, LEARN and Ornish.

Gold and colleagues[148] demonstrated the effects of a structured behavioural weight loss website (VTrim) compared with a commercial weight loss website (eDiets.com). The structured behavioural weight loss website (VTrim) consisted of a 6-month on-line therapist-led weight loss programme and 6-month on-line weight maintenance programme. Commercial weight loss website (eDiets.com) provided a calorie-controlled meal plan tailored to individual preferences, encouraged overweight or obese participants to follow their meal plan (my diet), recipe instructions and menu-specific grocery lists, supported exercise (my fitness) to provide progress weekly and monitored by experts and peers in Support central. After six months, weight change in eDiets vs VTrim was -4.1 kg (-4.4%) vs -8.3 kg (-8.9%), $p = 0.004$.

Haapala and colleagues[124] evaluated the short- and long-term effectiveness of weight loss in a mobile phone weight-loss programme in healthy overweight adults. At 12 months, the completed subjects' mean weight loss in the experimental group, Weight Balance® (-4.5 kg, -5.4%), was greater than control group (-1.1 kg, -1.3%). Consequently, weight loss between groups at 12 months was of a statistically significant difference ($p = 0.006$).

Heshka and colleagues[151] compared the effectiveness of a self-help programme and a WW weight loss in overweight and obese adults. Participants in WW received vouchers worth $9.00 to attend WW sessions. Subjects in the self-help programme had 20-minute consultations with a dietician at the first session and week 12 visits, received printed material about dietary principles and physical activity guidelines for weight loss and were offered other resources of weight loss information such as public library materials, web sites on the Internet and telephone numbers of health

promotion organisations. Average weight losses at 26 weeks, 1 and 2 years in WW compared with self-help participants were -4.8, -4.3 and -2.9 kg (-5%, -4.6% and -3.1%) vs -1.4, -1.3 and -0.2 kg (-1.5%, -4.6% and -3.1%), respectively, $p < 0.01$ at 26 weeks, $p < 0.001$ at 1 and 2 year (s). Therefore, at 26 weeks, participants' mean BMI in WW, compared with self-help participants was 1.7 vs 0.5 kg/m^2. At 1 and 2 years, participants' mean BMI in WW compared with self-help participants was 1.6 and 1.1 kg/m^2 vs 0.5 and 0.2 kg/m^2.[150]

Jebb and colleagues[152] compared weight loss of overweight or obese participants who had at least one additional risk factor for obesity-related disease in primary care referral to WW with standard care. Results showed that at 12 months, weight change in WW vs standard care was -5.06 kg (-5.8%) vs -2.25 kg (-2.6%), $p < 0.0001$.

Jolly and colleagues[17] evaluated the effectiveness of a range of weight loss programmes on weight loss. This involved eight interventions: WW, Slimming World (SW), Rosemary Conley (RC), Size Down (SD), Choice and Comparator (C), general practice (GP) and pharmacy (P). At 12 weeks, participants' mean weight loss in WW was -4.4 kg (-4.7%), Rosemary Conley -4.2 kg (-4.5%), Slimming World -3.6 kg (-3.8%), Choice -3.3 kg (-3.6 %), Size down -2.4 kg (-2.5%), Pharmacy -2.1 kg (-2.3%), Comparator (Exercise) -2.0 kg (-2.1%) and general practice -1.4 kg (-1.5%). Overweight or obese participants in WW (-2.4 kg, -2.5%, $p < 0.001$) and Rosemary Conley (-2.2 kg, -2.2%, $p < 0.05$) recorded statistically significant differences in mean weight loss when compared to a comparator group. Consequently, CWLPs were more likely to be effective than comparators; WW was the most successful of the eight weight loss interventions.

Luszczynska and colleagues[156] investigated the effects of the implementation intention prompt (IIP) on weight reduction. This study provided Weight Watchers (WW) with implementation intention prompt (IIP) conditions and found that at two months, overweight or obese women's weight loss in WW with IIP compared with control group was -4.2 kg (-4.7%) vs -2.1 kg (-2.4%) as well as BMI decrease 1.91 kg/m^2 vs 0.53 kg/m^2, $p < 0.05$.

Rock and colleagues[153] investigated whether a multifaceted commercial weight loss programme (Jenny Craig, JC) promotes greater weight loss in overweight or obese women compared with usual care. At 12 months, participants' mean weight loss in JC vs usual care control group (UC) was -7.3 kg (-7.8%) vs -0.7 kg (-0.7%), $p < 0.01$. Therefore, participants in the JC group lost significantly more weight than those in the UC group.

Rock and colleagues[154] studied whether a free prepared meal and incentivised structured weight loss programme as centre-based (CB) or telephone-based (TB) intervention promotes greater weight loss in overweight and obese women compared with usual care (UC). Participants in both CB (-8.2 kg, -8.9%) and TB (-6.7 kg, -7.2%) interventions reported significantly greater weight loss than those in the UC group.

Shuger and colleagues[155] study examined the effects of continuous self-monitoring and feedback of SenseWear™ Armband (SWA) alone and in combination with group weight loss (GWL) to improve weight loss over a 9-month period in sedentary overweight or obese adults. Participants' mean weight loss in all three intervention

groups, GWL (-1.86 kg, -1.83%), SWA alone (-3.55 kg, -3.5%) and GWL plus SWA (-6.6 kg, -6.6%), was statistically significantly different from Standard Care (-0.9 kg, -0.9%). As a consequence, participants who participated in GWL plus SWA experienced greater weight loss than those in other groups.

Truby and colleagues[126] compared the effectiveness of four commercial weight loss diets – WW, RC, Atkins and Slim-fast. The greatest participants' mean weight change was seen in the WW intervention group (-6.6 kg, -7.3%); weight change for Rosemary Conley was (-6.3 kg, -7.0%), Atkins (-6.0 kg, -6.2%), Slim-fast (-4.8 kg, -4.9%) and control (-0.6 kg, -0.7%). Although there were no statistically significant differences of mean weight loss over time, a significant difference was found when compared with the control group at $p < 0.001$.

Van Wier and colleagues[157] study examined the effects of a weight-management programme with personal counselling by phone or e-mail. Compared with a control group, overweight or obese participants' weight loss in the phone group was -0.8 kg whilst that in e-mail group was -1.7 kg over the 2-year study. The phone group in this study recorded a lower weight loss than e-mail group in the Rock and colleagues[154] study during the same period of trial.

Womble and colleagues[113] evaluated the effectiveness of eDiets.com (a commercial Internet weight loss programme) to improving weight. Two treatment groups were eDiets.com and Weight loss manual (a copy of LEARN programme); the average percentage of weight loss at 12 months in eDiets vs LEARN was -1.1% vs -4.1%, *p*

< 0.005. Therefore, participants in the manual group lost significantly more weight than those in eDiets.com.

Table 2.12 Study details of interventions for diet and exercise

Study	Participants	Interventions	Weight or BMI changes
Dansinger et al.[11] 2005, US N = 160 Single-centre randomised trial	Settings: Academic medical centre in Boston, Massachusetts Age 22-72 years, BMI 27-42 kg/m^2 81 women, 79 men Mean age 49 years Mean weight 100 kg Mean BMI 35 kg/m^2	40 participants each assigned to Atkins, Zone, Weight Watchers (WW) and Ornish Duration: 1 year	Atkins: -2.1 ± 4.8 kg (-2.1%) Zone: -3.2 ± 6.0 kg (-3.2%) WW: -3.0 ± 4.9 kg (-3.0%) Ornish: -3.3 ± 7.3 kg (-3.2%) $p < 0.01$ within group $p = 0.4$ among groups
Djuric et al.[145] 2002, US N = 48 Randomised pilot study (prospective trial)	Settings: Single-centre (Secondary care) Age 18-70 years Both women and men Age 36-70 years Mean weight 95.4 kg Mean BMI 35.5 kg/m^2	12 participants each in control (1), Weight Watchers: WW (2), individualised counselling (3), and combination of WW and individualised counselling (4) Duration: 12 months	Group 1: -0.85 ± 6.0 kg Group 2: -2.6 ± 5.9 kg Group 3: -8 ± 5.5 kg Group 4: -9.4 ± 8.6 kg $p < 0.05$
Foster et al.[147] 2009, US N = 69 Randomised study	Settings: Temple University Age 21-75 years, BMI 30-50 kg/m^2 49 women, 20 men Mean age 52.5 years Mean weight 111.2 kg Mean BMI 39 kg/m^2	35 patients in A commercially available weight loss programme: A prepackaged, portion-controlled diet plan (PCD: NutriSystem® DTM PCD) 34 patients in diabetes support and education (DSE) Duration: 3 months	PCD: -8.2 kg (95% CI: 9.5 to -6.7), -7.1% DSE: -0.6 kg (95% CI: -2.0 to 0.8), -0.4% BMI decreased PCD: 2.6 kg/m^2, 6.6% DSE: 0.4 kg/m^2, 1.0% $p < 0.0001$

Table 2.12 (continued)

Study	Participants	Interventions	Weight or BMI changes
Gardner et al.[117] 2007, US N = 311 Randomised trial	Settings: Local community in the US Age 25-50 years, BMI 27-40 kg/m^2 Only premenopausal women Mean age 41 years Mean weight 85 kg Mean BMI 32 kg/m^2	77 participants in Atkins group, 79 participants in Zone group, 79 participants in LEARN group, 76 participants in Ornish group Duration: 12 months	Atkins: -4.7 kg (95% CI: -6.3 to -3.1), -5.5% Zone: -1.6 kg (95% CI: -2.8 to -0.4), -1.9% LEARN: -2.2 kg (95% CI: -3.6 to -0.8), -2.6% Ornish: -2.6 kg (95% CI: -3.8 to -1.3), -1.9% p = 0.01
Gold et al.[148] 2007, US N = 124 RCT Face-to-face intervention	Settings: Website weight loss programme Age 18 years and older, BMI 25-39.9 kg/m^2 101 women, 23 men Mean age 47.7 years Mean weight 91.1 kg Mean BMI 32.4 kg/m^2	62 participants each in eDiets and VTrim groups Completers: 48 in eDiets.com, 40 in VTrim Duration: 12 months The first 6-month: Weight loss programme The last 6-month: Weight maintenance programme	At 6 months, eDiets: -4.1 ± 6.2 kg (-4.4%), VTrim: -8.3 ± 7.9 kg (-8.9%) p = 0.004 At 12 months, eDiets: -3.4 ± 5.8 kg (-3.7%), VTrim: -7.8 ± 7.5 kg (-8.6%) p = 0.034
Haapala et al.[124] 2009, Finland N = 124 RCT	Settings: University hospital, Kuopio Finland Age 25-44 years, BMI 25-36 kg/m^2 96 women, 28 men Mean age 38.05 years Mean weight 87 kg Mean BMI 30.5 kg/m^2	62 subjects each in experimental and control groups Completers: At 12 months, 42 subjects in experimental group (EG: Weight Balance) 40 subjects in control group (CG) Duration: 12 months	EG: -4.5 ± 5.0 kg (-5.4%) CG: -1.1 ± 5.8 kg (-1.3%) p = 0.006

Table 2.12 (continued)

Study	Participants	Interventions	Weight or BMI changes
Heshka et al.[150, 151] 2000, 2003 US N = 423 RCT	Settings: Multicentre (6 clinical research centres) Age 18-65 years, BMI 27-40 kg/m^2 358 women, 65 men Mean age 44.5 years Mean weight 93.7 kg Mean BMI 33.7 kg/m^2	211 subjects in commercial programme (Weight Watchers) 212 subjects in self-help group Duration: 26 weeks	Commercial programme: -4.8 ± 5.6 kg (-5.0%) Self-help group: -1.4 ± 4.7 kg (-1.5%) BMI decreased: Commercial programme: 1.7 kg/m^2 Self-help group: 0.5 kg/m^2 $p < 0.01$
Heshka et al.[150, 151] 2000, 2003 US N = 423 RCT	Settings: Multicentre (6 clinical research centres) Age 18-65 years, BMI 27-40 kg/m^2 358 women, 65 men Mean age 44.5 years Mean weight 93.7 kg Mean BMI 33.7 kg/m^2	211 subjects in commercial programme (Weight Watchers) 212 subjects in self-help group Duration: 24 months	At year 1 and 2, commercial programme:* -4.3 ± 0.4 kg (-4.6%) and -2.9 ± 0.5 kg (-3.1%) Self-help group:* -1.3 ± 0.4 kg (-1.4%) and -0.2 ± 0.4 kg (-0.2%) At year 1 and 2, BMI decreased: Commercial programme: 1.6 and 1.1 kg/m^2 Self-help group: 0.5 and 0.2 kg/m^2, respectively $p < 0.001$
Jebb et al. 2011,[152] UK N = 772 Multicentre, RCT with a parallel design	Settings: Primary care practices in Germany, Australia and UK Age at least 18 years, BMI 27-35 kg/m^2 668 women, 104 men Mean age 47.4 years Mean weight 86.7 kg Mean BMI 31.4 kg/m^2	378 participants in commercial programme (Weight Watchers) 395 participants in standard care Duration: 12 months	Commercial programme:* -5.06 ± 0.31 kg (-5.8%) Standard care:* -2.25 ± 0.21 kg (-2.6%) $p < 0.0001$

*mean ± SE

Table 2.12 (continued)

Study	Participants	Interventions	Weight or BMI changes
Jolly et al.[17] 2011, UK N = 740 8-arm RCT	Settings: 17 primary care trust in South Birmingham, England Aged ≥ 18 years White Europeans and all ethnic groups: BMI ≥ 28 kg/m^2 with comorbidities in or BMI ≥ 30 kg/m^2 without comorbidities South Asians: BMI ≥ 23 kg/m^2 with comorbidities or BMI ≥ 25 kg/m^2 without comorbidities 495 women, 245 men Mean age 49.3 years Mean weight 93.3 kg Mean BMI 33.6 kg/m^2	100 participants of each group for Weight Watchers (WW), Slimming World (SW), Rosemary Conley (RC), Size Down (SD), Choice and Comparator (C) 70 participants of each group for general practice (GP) and pharmacy (P) Duration: 12 weeks	WW: -4.4 kg (95% CI: 3.6-5.3), -4.7% SW: -3.6 kg (95% CI: 2.7-4.4), -3.8% RC:[a] -4.2 kg (95% CI: 3.2-5.2), -4.5% SD: -2.4 kg (95% CI: 1.7-3.1), -2.5% Choice: -3.3 kg (95% CI: 2.5-4.1), -3.6% C: -2 kg (95% CI: 1.2-2.8), -2.1% GP: -1.4 kg (95% CI: 0.4-2.3), -1.5% P: -2.1 kg (95% CI: 1.0-3.2), -2.3% $p \leq 0.01$, [a]$p < 0.05$
Luszczynska et al.[156] 2007, UK, Poland N = 55 RCT	Settings: Warsaw, Poland Age 18-76 years, BMI > 25 kg/m^2 Both women and men Mean weight 89 kg Mean BMI 33.2 kg/m^2	29 participants in control 27 participants in Weight Watchers with implementation intention prompt (IIP) conditions Duration: 2 months	Control: -2.1 kg (95% CI: 1.11-3.09), -2.4% IIP: -4.2 kg (95% CI: 3.19-5.07), -4.7% BMI decreased: Control: 0.53 kg/m^2 IIP: 1.91 kg/m^2 $p < 0.05$
Rock et al.[153] 2007, US N = 70 RCT	Settings: San Diego Age 18 years and older, BMI 25-40 kg/m^2 Only women Mean age 41 years Mean weight 92 kg Mean BMI 34 kg/m^2	35 participants each in intervention group (Jenny Craig: JC) and usual care control group (UC). At 12 months, 32 participants in intervention group 33 participants in usual care control group Duration: 12 months	JC: -7.3 ± 10.4 kg (-7.8%) UC: -0.7 ± 5.6 kg (-0.7%) $p < 0.01$

Table 2.12 (continued)

Study	Participants	Interventions	Weight or BMI changes
Rock et al.[154] 2010, US N = 442 RCT	Settings: US institutions at 4 study sites that consisted of 3 universities as University of California, Arizona, and Minnesota and one centre of health research, Oregon Age 18 years or older, BMI of 25 to 40 kg/m^2 Only women Mean age 44.3 years Mean weight 92 kg Mean BMI 33.9 kg/m^2	167 participants in centre-based intervention (CB: Jenny Craig) 164 participants in telephone-based intervention (TB) 111 participants in usual care group (UC) Completers: 151 participants in CB 153 participants in TB 103 participants in UC Duration: 24 months	CB: -8.2 kg (95% CI: -9.5 to -6.8), -8.9% TB: -6.7 kg (95% CI: -8.2 to -5.2), -7.2% UC: -2.1 kg (95% CI: -3.6 to -0.7), -2.3% $p < 0.05$
Shuger et al.[155] 2011, US N = 197 RCT	Settings: The greater Columbia, South Carolina area Age 18-64 years, BMI 25-45 kg/m^2 161 women, 36 men Mean age 46.9 years Mean weight 92.8 kg Mean BMI 33.3 kg/m^2	50 participants for standard care (SC) 49 for Group-based behavioural weight loss programme (GWL) 49 for Combined GWL and SWA group (GWL + SWA) 49 for SenseWear™ Armband alone group (SWA alone) Duration: 9 months	SC: -0.9 kg (-0.9%) GWL: -1.86 kg (-1.83%) GWL + SWA: -6.6 kg (-6.6%), $p < 0.0001$ SWA alone: -3.55 kg (-3.5%), $p = 0.0002$ BMI decreased, SC: -0.36 kg/m^2 GWL: -0.7 kg/m^2, $p = 0.03$ GWL + SWA: -2.28 kg/m^2, $p < 0.0001$ SWA alone: -1.17 kg/m^2, $p = 0.0005$

Table 2.12 (continued)

Study	Participants	Interventions	Weight or BMI changes
Truby et al.[126] 2006, UK N = 293 Multicentre randomised unblinded controlled parallel dietary intervention	Settings: Community based sample of healthy overweight and obese adults, 5-region centres at Surrey University, Bristol University, Nottingham University, Ulster (Caleraine) University and Queen Margaret University College, Edinburgh) Age 18-65 years, BMI 27-40 kg/m^2 214 women, 79 men Mean age 40.2 years Mean weight 89.4 kg Mean BMI 31.7 kg/m^2	57 participants in Atkins (A) 58 participants in Weight Watchers (WW) 59 participants in Slim-fast (SF) 58 participants in Rosemary Conley (RC) 61 participants in Control (C) Duration: 6 months	A: -6.0 ± 6.4 kg (-6.2%) WW: -6.6 ± 5.4 kg (-7.3%) SF: -4.8 ± 5.6 kg (-4.9%) RC: -6.3 ± 6.1 kg (-7.0%) Control: -0.6 ± 2.2 kg (-0.7%) $p < 0.001$
Van Wier et al.[157] 2011, Netherlands N = 1386 RCT	Settings: 7 Dutch service-sector companies Age ≥ 18 years, BMI ≥ 25 kg/m^2 457 women, 929 men Mean age 43 years Mean weight 93.2 kg Mean BMI 29.6 kg/m^2	462 participants in phone 464 participants in Internet 460 participants in control Completers: 263 in phone, 263 in Internet, 266 in control Duration: 2 years	Compared with control group: Phone lost 0.8 kg (95% CI: -1.5 to 0.03) $p = 0.059$ Internet lost 1.2 kg (95% CI: -1.9 to -0.4) $p = 0.004$
Womble et al.[113] 2004, US N = 47 RCT	Settings: University of Pennsylvania Age 18-65 years, BMI 27-40 kg/m^2 Both women and men Mean age 43.8 years Mean weight 90.7 kg Mean BMI 33.5 kg/m^2	23 participants in eDiets.com 24 participants in LEARN (Weight loss manual) At week 16 and 52, 23 participants each in both eDiets.com and LEARN (Weight loss manual) Duration: 12 months	At week 16 and 52, eDiets lost 0.9 ± 3.2 % (0.8 kg) and 1.1 ± 4.0 % (1.0 kg), respectively LEARN lost 3.6 ± 4.0 % (3.2 kg) and 4.0 ± 5.1 % (3.5 kg), respectively $p < 0.05$

2.4.3.3 Meal replacement

There were two RCTs for meal replacement with treatment lengths of 12 and 24 weeks – see Table 2.13.

Anderson and colleagues[144] compared effects of a standardised behavioural intervention using meal replacements (MRs), fruits and vegetables (MR-FV) and increased physical activity with a usual-care intervention on body weight change. The intervention group provided meal replacements, fruits and vegetables (MR-FV) as a low-energy diet whilst a control group received usual-care weight-loss counselling from an experienced or a registered dietician. At 24 weeks, obese participants' mean weight in MR-FV vs control group was -13.9 kg vs -0.7 kg (-13.9% vs -0.7%).

Donnelly and colleagues[146] compared the effectiveness of a phone-based and a traditional face-to-face clinic approach using meal replacement to achieve 10% weight loss at 12 weeks. Results of phone and clinic groups showed greater weight loss than the control group (-0.2%). This study confirmed that both a phone approach and the traditional weight management clinic yielded similar success at 10% weight loss of the initial weight at baseline.

Table 2.13 Study details of interventions for meal replacement

Study	Participants	Interventions	Weight or BMI changes
Anderson et al.[144] 2003, US N = 38 RCT	Settings: University medical centre Age 20-65 years, BMI 30-39.9 kg/m^2 29 women, 9 men Mean age 48 years Mean weight 99.5 kg Mean BMI 35.4 kg/m^2	16 participants in control group 22 participants in meal replacements, fruits and vegetables (MR-FV) Duration: 24 weeks	Control:* -0.7 ± 1.1 kg (-0.7%) MR-FV:* -13.9 ± 1.1 kg (-13%) $p < 0.0001$
Donnelly et al.[146] 2007, US N = 96 RCT	Settings: Weight management clinic Age 25-68 years, BMI 33.2 ± 3.8 kg/m^2 72 women, 24 men Median age: 53 years in phone, 52 years in clinic, 46 years in control groups Median weight: 102.5 kg in phone, 95.6 kg in clinic, 88.2 kg in control groups	25 participants in phone group 27 participants in clinic group 22 participants in control group Duration: 12 weeks	Median weight loss (range, %) in Phone: -10.6 kg (16.6, -10.4%) Clinic: -12.7 kg (19.9, -13.7%) Control: -0.25 kg (5.6, -0.2%) $p < 0.05$

*mean ± SE

2.4.4 Synthesis of findings

The synthesis of findings revealed that the potential elements which are important in effective weight loss were: 1) structure of interventions via diet and exercise, 2) support, 3) length of treatment and 4) other considerations such as adverse events and dropout rate.

This review compared the percentage weight loss across studies, particularly focusing on calorie restricted diets, exercise and support in the intervention groups. Those three elements are the essential criteria of any weight loss strategy, in order for CWLPs to be effective.

The diet was considered in terms of calorie restriction per day (total kcal/day). This element was primarily associated with the effectiveness of weight loss. Exercise and support are the complementary components in weight management. Exercise was associated with weight loss which, in addition to diet, was either taken as daily exercise or was optional. Providing support can encourage overweight or obese participants to lose weight via assistance from providers as well as the participants' ability at self-monitoring. All three elements will be considered with relevant examples from the review – see Table 2.14 and Table 2.15.

In this review of all weight loss interventions, there were 46 intervention arms, which included four arms consisting of a diet group;[119, 149] 39 arms consisting of a diet and exercise group;[11, 17, 113, 117, 124, 126, 145, 147, 148, 150-157] and three arms consisting of a meal replacement group[144, 146] – see Table 2.14 and Table 2.15. The effectiveness of CWLPs was evaluated using the percentage weight loss of at least 5% of the initial body weight for up to or more than three months. Where the weight loss interventions showed a weight loss of less than 5% this was taken to indicate an ineffective CWLP. This criterion was based on the NICE obesity guidelines.[15]

2.4.4.1 Structure of interventions: diet and exercise

Calorie restriction

Several CWLPs which specified calorie restriction per day appeared to be more effective than those with non-specified calorie restriction per day, in both short- and long-term treatments. Calorie restricted meal replacement programmes[144, 146] (1,200 kcal/day) and LL[119] (550 kcal/day) achieved weight loss of more than 5%. Nutrisystem restricted calories to 1,550 and 1,250 kcal each day for men and women, respectively.[147] Meanwhile SW,[17] RC,[17, 126] Zone,[11, 117] Ornish[11, 117] and LEARN,[113, 117] did not restrict total calorie intake per day and were shown to produce weight losses of less than 5%.

The most effective weight loss strategy for both a short- and long-term treatment was that of meal replacement programmes, yielding losses of 13.7%[146] and 13.9%,[144] respectively. This weight loss intervention consists of a very low or low calorie diet (HMR shakes, fruits and vegetables using a low energy diet with 5 meal replacements and 5 servings of fruit or vegetables). HMR (1,200 kcal/day) had a slightly lower calorie level than almost all diet and exercise groups (1,200-2,300 kcal/day) other than LL[119] (550 kcal/day). It can be seen that HMR would be more effective in producing weight loss than the remaining CWLPs.

Nutrisystem[147] (7.1%) was the only programme that restricted intake to 1,550 kcal/day in men and 1,250 kcal/day in women with mean age older than 50 years. Comparing Nutrisystem with a control, weight loss percentage from the Nutrisystem was significantly more when compared with a diabetes support and education programme (DSE, 0.4%).[147] This showed that DSE failed to achieve meaningful

weight loss. The reason for this is likely to be that DSE included only lessons about diet and exercise support. Such support was ineffective as participants possibly due to lower adherence in this programme compared with the weekly support provided by the Nutrisystem, resulted in minimal weight loss by DSE participants.

Regarding the remaining weight loss interventions for long-term treatment, seven interventions, which restricted total calorie intake per day, were effective, but not more so than meal replacement. These were JC[153, 154] (7.8% and 8.9%), VTrim[148] (8.9%), telephone-based programme[154] (7.2%), RC[126] (7.0%), GWL and SWA[155] (6.6%) and Weight Balance[124] (5.4%), respectively. JC[154] low-calorie diet restriction was 1,200-2,300 kcal/day whilst VTrim[148] consisted of reducing energy intake by 1,000 kcal/day. RC[126] included a low-calorie exchange diet (1,200 kcal/day) based on telephone-based intervention[154] which consists of a low- or very low-calorie diet (1,200-2,000 kcal/day) with reducing fat intake by 20%-30%. Lastly, Weight Balance[124] reduces food intake by 800-1,500 kcal/day. All four interventions of JC, VTrim, RC and telephone-based weight loss interventions included daily exercise and weekly individual support. Only Weight Balance included quarterly support – see Table 2.15.

Weight loss interventions which failed to achieve meaningful weight loss, such as Zone and Ornish,[11, 117] may have done so because such programmes did not restrict participants' in total calorie level per day.

Similarly, a telephone-based weight loss intervention (1.5%)[157] had a weight loss lower than 5% of the initial weight. The reason for this may be that participants in

this intervention received information on nutrition and exercise in the form of a workbook. Although participants had weekly one-to-one contact, via telephone, with health care providers, there were no restrictions on diet or exercise. It is therefore possible to conclude both the restriction of calorie and structured exercise is likely to lead to greater weight loss.

Structured exercise

Either high-impact or low-impact exercise, added to diet for weight loss, appeared to be another important component for the success of CWLPs. With exercise offered for participants as an optional activity appearing to be less effective than in programmes that encouraged weekly exercise (2,000 kcal/week)[144, 146] especially when participants were expected to record the calories burned in physical activity. This restricted exercise may be a reason why meal replacement was found to be more effective than other programmes. For the remaining weight loss interventions, physical activity was prescribed, such as, 30-60 minutes per day on 5-7 days each week. Therefore, the effectiveness of meal replacement and the diet and exercise group was greater than in the diet group, except for one intervention (LL)[119] which provided high restriction of total calorie level intake per day.

In summary, those CWLPs which resulted in an effective weight loss of at least 5% of the entry body weight involved total calorie restriction per day, daily exercise and weekly support. In contrast, those CWLPs that resulted in a weight loss of less than 5% of the initial body weight tended to have no calorie restriction per day on diet, optional exercise and offered only monthly or quarterly support.

Table 2.14 Key elements of weight loss interventions for short-term treatment

Study and Programme	Types of providers	Calorie restriction (Total kcal/day)	Exercise (Daily or Optional)	Description of support	Dropout (%)	Weight change (%)
Diet						
Green[149]						
Supported dieters	Dietician	Calorie restricted and Balanced diet: Low fat, Low carbohydrate	DNR*	Weekly group session	DNR*	3.3**
Unsupported dieters	No provider	Calorie restricted and Balanced diet: Low fat, Low carbohydrate, planned by participants	DNR*	Weekly group session	DNR*	2.9**
Control	DNR*	Non-dieting	DNR*	Weekly group session	DNR*	0.07**
Diet and exercise						
Foster[147]						
Nutrisystem	Physician	Portion-controlled diet plan, prepakaged Nutrisystem D™ PCD (Women: 1250, Men: 1550)	Daily principal walking start at week 4	Weekly group session led by health care professional	2.9	7.1
Diet support and education (DSE)	-	-	Daily principal walking start at week 16	Monthly group session led by health care professional	0	0.4

*DNR = Did not report

**Not significant difference between groups

Table 2.14 (continued)

Study and Programme	Types of providers	Calorie restriction (Total kcal/day)	Exercise (Daily or Optional)	Description of support	Dropout (%)	Weight change (%)
Luszczynska[156]						
WW + Implementation intention prompt	Group supporter	Low-calorie, exchange diet, clients prepare own meals (1200-1600)	Daily	Behaviour weight control methods: Weekly group and social support + Implementation intention prompt	DNR*	4.7
Weight Watchers (WW)	Dietician	Low-calorie, exchange diet, clients prepare own meals (1200-1600)	Daily	Behaviour weight control methods: Weekly group and social support	DNR*	2.4
Jolly[17]						
Weight Watchers	Dietician	Low-calorie, exchange diet, clients prepare own meals (1200-1600)	Daily	Behaviour weight control methods: Weekly group and social support	30	4.7
Slimming World (SW)	Food advisor, other members	Eat low energy dense food, control high energy dense food, extra fibre	Daily	Email, telephone and group support, individual support , weekly contact	40	3.8
Rosemary Conley (RC)	Food advisor, other members	Low-calorie, exchange diet	Daily	Role modelling, group, telephone, website and individual support, weekly contact	50	4.5
Size down	Trained worker	Balanced diet	Daily	NHS group based programme, biweekly contact	50	2.5

*DNR = Did not report

Table 2.14 (continued)

Study and Programme	Types of providers	Calorie restriction (Total kcal/day)	Exercise (Daily or Optional)	Description of support	Dropout (%)	Weight change (%)
Jolly[17] (continued)						
Choice	DNR*	Choose 1 of 6 interventions	Optional	DNR	26	3.6
General practice (Public)	General practitioner	Reducing calorie intake	Daily	Self-monitoring, weekly contact	54	1.5
Pharmacy (Public)	Pharmacist	Reducing calorie intake	Daily	Self-monitoring, weekly contact	46	2.3
Comparator (Exercise)	-	-	Daily	No appointment and individual advice and support	DNR*	2.1
Meal replacement						
Donnelly[146]						
Phone group	Licensed physician and other health care providers	Low-calorie or very low calorie diet, MR products (1200-1500)	Daily (2000 kcal/week)	Weekly one-to-one contact with telephone	16	10.4
Clinic group	Licensed physician and other health care providers	Low-calorie or very low calorie diet (1200-1500)	Daily (2000 kcal/week)	Group session, weekly classes	15	13.7

*DNR = Did not report

Comparing all weight loss interventions with their controls, over four-fifths of all interventions produced statistically significant differences in weight loss compared with control groups. Three key elements in controls were different from the active interventions. The percentage weight change of controls in 20 studies ranged from 0.07%-2.1% for a short-term treatment to 0.7%-4.4% for a long-term treatment. For example, the control groups in four studies failed to achieve any meaningful weight loss e.g. low-carbohydrate/high-protein diet[119] (1.8%), WW[156] (2.4%), LEARN[113] (4%), eDiets[148] (4%). However, the percentage weight loss in two controls was greater than that in the interventions. Those controls were found in Womble and colleagues[113] study (4% in LEARN vs 1.1% in eDiets) and Jolly and colleagues[17] (2.1% in comparator vs 1.5% in General Practice). Possible reasons for such results are described below.

Although eDiets and LEARN failed to achieve meaningful weight loss, it was useful to compare their elements in terms of effectiveness.[113] Considering key elements in eDiets, its structure was not step-by-step as with LEARN. Participants in LEARN needed to keep food records and count calories, whilst participants in the eDiets programme self-monitored and were not asked to record their total calorie intake per day; therefore, these activities in LEARN brought about a greater weight loss than those in eDiets. If participants in the Internet weight loss intervention had been required to keep daily records for total calorie intake per day in combination with exercise and the similar support, the results would probably have been similar. Therefore, this study showed that total calorie restriction per day and daily exercise with support are the main elements in any effective weight loss programme.

In the study of Jolly and colleagues,[17] although General Practice included reducing calorie intake, daily exercise and weekly contact with a general practitioner, participants' percentage weight change in this intervention was lower than the comparator (exercise). Additionally, there was no individual advice and support provided for the comparator group. Participants in this comparator group registered greater weight loss than those in the General Practice programme. This study claimed that participants in the comparator group were more likely to exercise and to highly adhere to this programme – resulting in losing weight. Meanwhile participants in General Practice may be less inclined to take exercise, which affected their weight loss.

Table 2.15 Key elements of weight loss interventions for long-term treatment

Study and Programme	Types of providers	Calorie restriction (Total kcal/day)	Exercise (Daily or Optional)	Description of support	Dropout (%)	Weight change (%)
Diet						
Rolland[119]						
LighterLife (LL)	Trained LL counsellor	Very low calorie diet (550): 36% carbohydrate, 36% protein, 28% fat	Daily	Long-term behaviour modification with group, telephone and email support, monthly contact	58.8	9.5, 12.3 (3 and 9 months)
Low-carbohydrate/high-protein diet (LCHP)	Dietician, doctor	Low-carbohydrate/high-protein diet (800-1500): 20% carbohydrate, 40% protein, 40% fat	Daily	Alternative approach by LCHP or prescription medication	47.4	2.5, 1.8 (3 and 9 months) 1.8
Diet and exercise						
Dansinger[11]						
Atkins	Dietician and physician advice	Carbohydrate restriction: Low carbohydrate	Daily	Supplements, exercise and external support, weekly contact	48	2.1*
Zone	Dietician and physician advice	Macronutrient balance: 40% carbohydrate, 30% fat, 30% protein	Daily	Supplements, exercise and external support, weekly contact	50	3.2*

*Not significant difference between groups

Table 2.15 (continued)

Study and Programme	Types of providers	Calorie restriction (Total kcal/day)	Exercise (Daily or Optional)	Description of support	Dropout (%)	Weight change (%)
Dansinger[11] (continued)						
WW	Dietician and physician advice	Low-calorie, exchange diet, clients prepare own meals (1200-1600)	Daily	Behaviour weight control methods: Weekly group and social support	53	3.0*
Ornish	Dietician and physician advice	Fat restriction	Daily	Supplements, exercise and external support, weekly contact	25	3.2*
Djuric[145]						
WW	Dietician	Low-calorie, exchange diet, clients prepare own meals (1200-1600)	Daily	Behaviour weight control methods: Weekly group and social support	72	2.6
Individualised counselling	Registered dietician	Low-calorie, exchange diet, clients prepare own meals (1200-1600)	Daily	Weekly 1-3 months, biweekly 3-6 months, Monthly after 6 months one-to-one counselling using Bandura's social cognitive theory	DNR**	8 kg (Did not report the initial weight)
WW + Individualised counselling	Dietician and physician advice	Low-calorie, exchange diet, clients prepare own meals (1200-1600)	Daily	Behaviour weight control methods: Weekly group and social support + individualised counselling using Bandura's social cognitive theory	53	9.4 kg (Did not report the initial weight)

*Not significant difference between groups

**DNR = Did not report

Table 2.15 (continued)

Study and Programme	Types of providers	Calorie restriction (Total kcal/day)	Exercise (Daily or Optional)	Description of support	Dropout (%)	Weight change (%)
Djuric[145] (continued)						
Control	-	Received "Action Guide to Healthy Eating" and "Food Guide Pyramid" pamphlets (no dietary instructions)	No exercise instructions	-	DNR**	0.85
Gardner[117]						
Atkins	Dietician and physician advice	Carbohydrate restriction: Low carbohydrate	Daily	Supplements, exercise and external support, weekly contact	12	5.5*
Zone	Dietician and physician advice	Macronutrient balance: 40% carbohydrate, 30% fat, 30% protein	Daily	Supplements, exercise and external support, weekly contact	23	1.9*
Ornish	Dietician and physician advice	Fat restriction	Daily	Supplements, exercise and external support, weekly contact	22	1.9*
LEARN	Registered dietician	The LEARN Manual for Weight Management: 55-60% carbohydrate, 10% fat	Daily	Specific energy restriction goal, weekly contact	24	2.6*

*Not significant difference between groups

Table 2.15 (continued)

Study and Programme	Types of providers	Calorie restriction (Total kcal/day)	Exercise (Daily or Optional)	Description of support	Dropout (%)	Weight change (%)
Gold[148]						
eDiet	Company-trained counsellor and company dietician	Low-calorie diet, modified eating by virtual dieticians, clients prepare own meals (1200-1300)	Daily	Individual and group online support, weekly contact	35	4.4
VTrim	Therapist	Modified eating: Reduced energy intake up to 1000 kcal/day	Daily exercise up to 1000 kcal/day	Individual and group online support, weekly contact	23	8.9
Haapala[124]						
Weight Balance	Nurse	Reducing food intake (800-1500)	Daily	Modified phone-operated weight loss programme, quarterly visit	27	5.4
Control	No provider	No specific diet instruction	No specific exercise instruction	No intervention	35	1.3
Heshka[150, 151]						
WW	Dietician	Low-calorie, exchange diet, clients prepare own meals (1200-1600)	Daily	Behaviour weight control methods: Weekly group and social support	16	5.0, 4.6, 3.1 (H at 26 weeks, 1 and 2 year)[150, 151]

Table 2.15 (continued)

Study and Programme	Types of providers	Calorie restriction (Total kcal/day)	Exercise (Daily or Optional)	Description of support	Dropout (%)	Weight change (%)
Heshka[150, 151] (continued)						
Self-help	Dietician	Guideline for diet	Guideline for exercise	Counselling at the first visit and week 12	16	1.5, 1.4, 0.2 (26 weeks, 1 and 2 years)
Jebb[152]						
WW	Dietician	Low-calorie, exchange diet, clients prepare own meals (1200-1600)	Daily	Behaviour weight control methods: Weekly group and social support	39	5.8
Standard care	Primary care professional	Diet advice	Exercise advice	Used national clinical guideline	46	2.6
Rock[153]						
Jenny Craig (JC)	Company-trained counsellor	Low-calorie diet, prepackaged JC meals only (1200-2300)	Daily	Individual sessions, weekly contact	8.6	7.8 (12 months)
Usual care	Dietician	Received diet guideline without instruction	Received exercise guideline without instruction	Consultation at the initial visit and at week 16	5.7	0.7 (12 months)

Table 2.15 (continued)

Study and Programme	Types of providers	Calorie restriction (Total kcal/day)	Exercise (Daily or Optional)	Description of support	Dropout (%)	Weight change (%)
Rock[154]						
Jenny Craig (JC)	Company-trained counsellor	Low-calorie diet, prepackaged JC meals only (1200-2300)	Daily	Individual sessions, weekly contact	4.7	8.9 (24 months)
Telephone-based	Licensed physician and other health care providers	Low-calorie or very low calorie diet (1200-2000), low fat (20-30%)	Daily	Weekly one-to-one contact with telephone	6.7	7.2 (24 months)
Usual care	Dietician	Received diet guideline without instruction	Received exercise guideline without instruction	Consultation at the initial visit and at week 16	8.8	2.3 (24 months)
Shuger[155]						
Group-based behaviour weight loss programme (GWL)	Programme facilitator	Healthy eating	Optional	Group-based behaviour modification, monthly contact	30	1.8
SenseWear Armband (SWA) alone	Programme facilitator	Healthy eating	Daily	Personalised weight management, monthly contact	30	3.5

Table 2.15 (continued)

Study and Programme	Types of providers	Calorie restriction (Total kcal/day)	Exercise (Daily or Optional)	Description of support	Dropout (%)	Weight change (%)
Shuger[155] (continued)						
GWL + SWA	Programme facilitator	Healthy eating	Daily	Group-based behaviour modification and personalised weight management, monthly contact	30	6.6
Standard care	No provider	Healthy eating	Daily	Received self-directed weight loss manual	48	0.9
Truby[126]						
Atkins	Dietician	Carbohydrate restriction: Low carbohydrate	Daily	Supplements, exercise and external support, weekly contact	30	6.2
WW	Dietician	Low-calorie, exchange diet, clients prepare own meals (1200-1600)	Daily	Behaviour weight control methods: Weekly group and social support	29.8	7.3
Rosemary Conley (RC)	Food advisor, other members	Low-calorie, exchange diet (1200)	Optional	Role modelling, group, telephone, website and individual support, weekly contact	19	7.0
Slim-fast	DNR**	Low-calorie or very low calorie diet, MR products (1200)	Optional	Support pack with group session, weekly classes	19	4.9
Control	DNR**	Maintained diet	Maintained exercise	No intervention	34.4	0.7

Table 2.15 (continued)

Study and Programme	Types of providers	Calorie restriction (Total kcal/day)	Exercise (Daily or Optional)	Description of support	Dropout (%)	Weight change (%)
Van Wier[157]						
Telephone-based	Dietician, physical activity scientist	Received information on nutrition in the workbook form	Received information on exercise in the workbook form	Weekly one-to-one contact with telephone	43	1.5
Internet	Dietician, physical activity scientist	Accessed programme online without prescription of diet	Accessed programme online without prescription of exercise	Self-monitoring, goal setting, 4 months per contact	46.7	2.0
Control	No provider	Self-help diet	Self-help exercise	Self-help	46.5	1.8
Womble[113]						
eDiets	Company-trained counsellor and company dietician	Low-calorie diet, modified eating by virtual dieticians, clients prepare own meals (1200-1300)	Daily	Individual and group online support, weekly contact	34	1.1
LEARN	Registered dietician	The LEARN Manual for Weight Management: 55-60% carbohydrate, 10% fat	Daily	Specific energy restriction goal, weekly contact	34	4.0

Table 2.15 (continued)

Study and Programme	Types of providers	Calorie restriction (Total kcal/day)	Exercise (Daily or Optional)	Description of support	Dropout (%)	Weight change (%)
Meal replacement						
Anderson[144]						
Meal replacement, fruits and vegetables (MR-FV)	Licensed physician and other health care providers	Low-calorie or very low calorie diet, MR products (1200)	Daily (2000 kcal/week)	Group session, weekly classes	18	13.9
Usual care	Dietician	Nutritional balance	DNR**	Counselling monthly	18	0.7

**DNR = Did not report

2.4.4.2 The role of support

Although support is not the most essential element when deciding the effectiveness of a weight loss programme, it is certainly a component of sound weight management.[158] Support is an approach for monitoring weight reduction in individual or group meetings.

Most weight loss interventions were supported by health care providers (dieticians and other health care professionals), groups and media based efforts. Sixty-three percent of all programmes were supported by dieticians or other health care providers – see Table 2.16.

Table 2.16 Key supports for all 20 studies classified by head-to-head intervention delivery

Intervention delivery*	Total number	Studies were supported by					No support
		Providers	Group	Internet	Telephone	External	
Diet	8	2	2	2	2	-	-
Diet and exercise	45	13	11	7	7	5	2
Meal replacement	1	1	-	-	-	-	-
Total	54	16	13	9	9	5	2

*Many studies had more than one type of support.

Sixteen studies of interventions delivering diet and exercise (83% of these including support in some form) received support through the health care provider, group or social support, the Internet, telephone and external (book) support, respectively. There were 46 interventions in all studies, 36[11, 17, 113, 117, 119, 124, 126, 144-154, 156, 157] of which were supported by health care professionals, whilst seven interventions[17, 119, 153-156] were supported by non-health care professionals such as a group supporter,

trained worker or company counsellors and programme facilitators. Two interventions[17, 126] had no report of support, whereas no provider was reported in one intervention.[149] These data would appear to recommend health care providers (dieticians or physicians) offer support via counselling and advice, which can affect weight loss improvement. However, it is possible to conclude the combination of support with both the restriction of calorie intake and structured exercise is likely to lead to greater weight loss. This may reflect that support from health care providers is an important component when aiming to maintain weight loss in combination with diet and exercise.

In the diet and exercise group, participants received several types of support, depending on the particular diet and exercise programme. For example, VTrim[148] and JC[153, 154] encouraged participants via the Internet, to communicate with health care providers so that they could avail themselves of counselling. Although eDiets[113, 148] advised participants via the Internet, this intervention had a lower weight loss than VTrim at the end of one year. The likely reason for this deficit was that the eDiets' programme was supported by company-trained counsellors whilst VTrim was led by a therapist. The eDiets programme did not specifically ask participants to record their calorie intake; nor did they require records of daily calorie intake to be kept,[113] unlike VTrim which provided bi-weekly meetings and support components via the website. This would suggest that health care providers' support through the Internet is an important component for maintaining weight loss in the diet and exercise group.

2.4.4.3 Length of treatment

One of the key variables in any weight loss programme is the issue of 'length of treatment'; in other words how long any given participant keeps to that programme. Evidence from WW[17, 126, 150-152] serves to illustrate the relationship between weight loss and duration of participation. If a 5% loss of weight in any given period is the ultimate goal, WW yielded the following data:

- At three months a loss of 4.7%[17]
- At six months a loss of 5%[151] and 7.3%[126]
- At one year a loss of 5.8%[152]
- At two years a loss of 4.6%[150] and 3.0%[150]

It seems reasonable to suggest that, other things being equal, there is a positive relationship between weight loss and length of programme participation, with optimal results coming between six months and one year.

2.4.4.4 Other considerations

Adverse events

Five interventions in four studies – Atkins,[11] Zones,[11] WW,[11, 150, 152] Ornish[11] and meal replacement[144] – mentioned adverse events. None of the serious adverse events was found in four interventions: Dansinger and colleagues[11] study, i.e. WW, Atkins, Zone and Ornish; WW investigated by Heshka and colleagues[150] as well as Jebb and colleagues[152] studies reported no adverse events found.

For adverse events associated with meal replacement, Anderson and colleagues[144] reported participants' adverse events were higher than 50% in both groups, and were related to dietary problems and constipation. Participants in the control group (56.3%) had less adverse events than those in MR-FV group (59.1%). Nevertheless, any adverse events that occurred in the remaining study were not reported. This may be a reflection of minor adverse events, which are not related to either dropout rate or effective weight loss.

Dropout rate

The lowest dropout rate was from Nutrisystem[147] (2.9%) followed by JC (4.7%,[154] 8.6%[153]) and a telephone-based[154] (6.7%) programme. On the other hand, the dropout rates exceeded 50% for some interventions such as LL[119] (59%), General Practice[17] (54%), WW[11] (53%) and Zone[11] (50%). The dropout rates in the remaining interventions[11, 17, 113, 117, 124, 126, 144, 146, 148, 150-152, 155, 157] were similar to those in control groups[113, 119, 124, 126, 144, 146, 148, 150-152, 155, 157] ranging between 11% and 49%.

Interestingly, it would appear that standard treatment had a low dropout rate compared to CWLPs. For instance, the dropout rate in Diabetes support and education (DSE: control)[147] was 0%, with an accompanying reported weight loss of 0.4%. Usual care in the study by Rock and colleagues had a low dropout rate of 5.7%[153] and 8.8%[154] respectively, whilst none of the controls had dropout rates higher than 50% – see Table 2.14 and Table 2.15.

Although 85% of all studies reported some level of dropout rate, the dropout rate was not related to the effective weight loss. For example Nutrisystem[147] (7.1%), which

showed the lowest dropout rate (2.9%), had a lower percentage weight loss than meal replacement[144] (13.9%) which reported an 18% dropout rate. In contrast, the 12.3% of weight change in LL[119] was accompanied by an attrition rate of three-fifths (59%). It appears that the interventions mainly had relatively lower dropout rates of between 11%-49%, which may be related to the provision and receipt of weekly support – see Table 2.14 and Table 2.15.

2.4.4.5 Publication bias

Easterbrook et al.[159] classified 100 as the cut off point between smaller and larger sample sizes. Outcomes for publication bias will be reported only as percentage differences.

Eleven (55%) of the randomised studies involved sample sizes of at least 101 participants. Nine[17, 124, 126, 148, 150-152, 154, 155, 157] (82%) studies reported significant outcomes, whilst two[11, 117] (18%) studies reported non-significant outcomes. For studies with a sample of less than 100, eight[113, 119, 144-147, 153, 156] (89%) studies yielded statistically significant differences in outcomes across groups whilst one[149] (11%) study showed non-significant outcomes. Over four-fifths of all studies presented statistically significant differences, which were interpreted as representing no publication bias – see Table 2.17.

Table 2.17 Characteristics of 20 studies classified by statistical significance

Characteristics of sample size	Outcomes with statistical significance		Total
	Significant	Not significant	
< 100	8	1	9
≥ 101	9	2	11

2.5 Discussion

2.5.1 Main findings

This review identified 20 studies which considered the effectiveness of CWLPs on weight or BMI change in overweight and obese adults. The majority of the studies were conducted in the US. Over four-fifths of all studies included both men and women participants. Over two-thirds of all studies involved participants aged between 40 and 50 years with a mean BMI of 30-34.9 kg/m^2 at baseline (obesity class I). The interventions mainly lasted longer than three months. Four-fifths of the studies included the delivery of diet and exercise programmes. The remaining interventions were diet or meal replacement.

Provision of support for the diet and exercise groups also featured as a key intervention component. Several support initiatives were found in diet and exercise groups. Most support was provided by health care professionals, including dieticians, physician/doctors, therapists, pharmacists, nurses or food advisors (nutritionists). Support was also provided by non-health care professionals such as a group supporter, trained worker or facilitator.

The majority of primary outcome measures related to weight loss or weight change. Less than one-fifth of the studies measured both weight and BMI as primary outcome indicators. Seventeen studies demonstrated a statistically significant difference between CWLP and a control group. Twelve studies successfully achieved weight loss of at least 5% of the initial body weight, whilst eight did not achieve this successful reduction in this primary outcome. Only one fifth of the studies reported adverse events. The majority of studies reported dropout rated ranging of between 11% and 49%.

Overall, the majority of studies contained a low risk of bias (n = 17, 81%) whilst 14% (n = 3) were unclear and 5% registered high risk of bias.

2.5.1.1 General discussion

Based on the findings from 20 studies, this systematic review provides information about CWLPs weight loss interventions, particularly those based on diet (total kcal/day), exercise and support. Over half of all studies meaningfully targeted weight loss of at least 5% of the baseline body weight. From this finding, it would seem that calorie restriction is more effective in body weight reduction than the macronutrient composition of the diet.

Overall, judgements about weight loss interventions across studies can be made by considering the elements of interventions provided and the duration of the programme. The duration of studies ranged from 2 months to 24 months. Participants who took part in the CWLPs for up to three months lost weight ranging from 2.1 to 12.7 kg, whilst those who attended over three months lost weight ranging from 0.8 to

13.9 kg. There appears to be little difference in the overall amount of weight loss across different lengths of programmes. For instance, the percentage change in weight of participants in short term meal replacement programmes (10.4%-13.7%)[146] is not substantially different from longer term meal replacement programmes (13.9%).[144]

The studies were difficult to directly compare as the interventions varied considerably, which made concluding which weight loss programme pattern is the most effective more complex. However, this review compared the effectiveness of three categories based on key elements provided in the interventions: diet (total kcal/day), exercise and support, as well as taking into account other outcomes such as adverse events and the dropout rate. The percentage of weight change was considered in terms of significant differences and meaningfully amounts of weight loss as defined in the NICE guideline.[15]

The differences in diet, exercise and support in the programmes potentially affected the weight loss. The most effective CWLP, for a short term treatment, involved meal replacement, when compared with diet programmes and diet and exercise programmes. This intervention involved HMR shakes as diet (energy intake 1,200 kcal/day), exercise (energy expenditure 2,000 kcal/week) and weekly health care provider support although the dropout rate of HMR was 15%-18%.[144, 146] However this claim needs to be considered with caution as it was only based on two studies in the US. Despite this, the important elements of this intervention can be taken forward to other programmes such as specifying calorie intake, exercise amounts and providing weekly support.

A VLCD alone was more effective than diet and exercise groups in terms of percentage change in weight. This programme can be appropriate for participants who have BMI ≥ 30 kg/m^2 and struggle to exercise due to their size. However, the dropout rates in diet alone groups were higher than 50%. This may be because the participants had difficulty keeping to such a very low-calorie daily diet.

Although the percentage change in weight of participants in the diet and exercise group (2.4% to 7.1% for a short-term treatment, 1.5% to 8.9% for long-term treatment) was lower than with meal replacement (10.4% to 13.7% for a short-term treatment, 13.9% with long-term treatment), the structure of interventions is similar to meal replacement. Both groups were provided with daily exercise targets and weekly support.

Another intervention in diet and exercise group, Nutrisystem[147] yielded a 7.1% weight loss for a short-term treatment and had the lowest dropout rate (2.9%). This intervention showed participants' mean age to be older than 50 years, which may be related to older participants being more able or motivated to commit to remaining in the trial for longer. This study was for obese patients with type 2 diabetes with a BMI 30-50 kg/m^2. Their health condition may also have been a motivating factor for remaining in the programme. This programme had different levels of calorie constraint for men (1,550 kcal/day) and women (1,250 kcal/day), so this suited each gender. Although this intervention produced a lower weight loss compared with meal replacement, it may be more appropriate for obese patients with BMI 30-50 kg/m^2 than a meal replacement programme as, although there is a higher calorie intake and a lower weight loss, there was a very low dropout rate. Support in this programme

was led by health care professionals, similar to other diet and exercise groups and the meal replacement model.

The main points to take into account when considering the effectiveness of CWLPs for a long term treatment were in diet and exercise groups, and consisted of calorie level (energy intake 1,200-2,300 kcal/day), exercise (weekly) and several types of support. JC[154] was considered to be the most effective weight loss programme; however, this intervention did not report about its generalisability. This study was conducted in the US as the programme is only offered there. Given the effectiveness of the programme it is likely to be taken up in other countries. Similarly, VTrim[148] was as effective as JC when taking into account calorie level per day, exercise, support and no reports of adverse events. This intervention was also conducted in the US and although this intervention was more economical in terms of saving costs of transport and staff costs, not all potential participants may want an Internet-based programme or have access to the resources needed.

Standard treatment had a low dropout rate compared to CWLPs, perhaps due to the less restrictive diet and lack of demands about exercise. This review found that participants may find it difficult to stick to a very low-calorie daily diet in a CWLP – thus levels of support in such programmes may need to be increased.

Requirements to maintain a balanced diet (Zone: 40% carbohydrate, 30% fat, 30% protein) through good healthy eating without calorie restriction allows easier compliance but this results in weight loss at a somewhat slower rate than with CWLPs employing a low-calorie diet such as WW (1,200-1,600 kcal/day), RC, JC

(1,200-2,300 kcal/day), eDiets (1,200-1,300 kcal/day) or Nutrisystem. High carbohydrate intake programmes such as LEARN (55%-60% carbohydrate, 10% fat) are appropriate for obese people with comorbid health risks, but are unsuitable for a lifelong diet because this can lead to dietary deficiency and also may be difficult to adhere to.

2.5.1.2 Other issues and methodological concerns

The concept of this review was to focus on randomised trials. The study identification was arranged by taking into account the different multicomponent interventions. Although it was difficult to compare a variety of CWLPs, this review was able to compare the effectiveness of the various settings across studies, based on the main elements of the programmes namely, diet, exercise and support. Settings did not appear to be a key element that affected the achievement of weight loss, so the findings could be generalised to other settings.[17, 150-152]

Recruiting people to participate in the interventions was mostly done via media advertisements. Seven studies reported the use of incentives to assist with recruitment[17, 117, 126, 150, 151, 153, 154, 157] such as that reported by Heshka and colleagues[150, 151] where they gave participants a $9 weekly attendance reward. The dropout rate was 16% at 26 weeks, one and two years with 5%, 4.6% and 3.1% weight loss, respectively. This suggests that there may be a positive relationship between incentives and the likelihood of dropping out.

Achieving weight-loss goals may depend on whether participants in the CWLPs had previously attempted weight loss and the duration of the period of their being overweight or obese. Unfortunately, none of the included studies reported these characteristics and thus the effectiveness of the programmes, in the light of this issue, is unknown. In addition, it is possible that the roles of health care providers may change. Practices in different countries vary, even within the countries themselves. This review was unable to provide sufficient information on the process of training providers, a deficit also noted by Loveman and colleagues.[124]

In terms of methodological rigour, over half of the studies were assessed to be at a low risk of bias. However very few were blinded studies as well as the previous systematic review had a few studies for blinding of the assessor.[160] Realistically, it was very hard to blind people who participated in the weight loss programmes because they will tend to know what they are eating and how much exercise they take. Similarly, the previous systematic review of weight loss interventions reported adequate concealment of allocation in only a few studies.[160] There appeared to be little selective reporting of outcomes from the studies or of inadequate randomisation procedures.

This review showed mainly the number of interventions with statistical significance. Nevertheless, Easterbrook et al.[159] suggested that small sample size should be used with great caution.

2.5.2 Strengths, limitations and generalisability

2.5.2.1 Strengths

This is the first systematic review to determine the effectiveness of CWLPs in helping overweight and obese adults worldwide. The main strength of this study lies in its contribution to providing insight into CWLPs and what they offer to overweight or obese populations, by focusing attention on drawing out the relevant literature about CWLPs, which are essentially directed towards achieving weight loss.

The studies included in the review were obtained by following the principles for conducting a systematic review. The methods were set out in a research protocol, which defined the research question, a comprehensive search of databases, inclusion and exclusion criteria, the data extraction process, quality assessment and data synthesis. The review team undertook their task using the original articles published. The research protocol was informed by comments and advice from the review team. The main reviewer (SS) reviewed all articles which were rechecked by a second reviewer (HB). The review team also commented on the review report. All articles were critically appraised and reported in a consistent and transparent manner. Therefore, this review was inclusive in terms of efficacy in CWLPs provided they warranted inclusion in this review. Studies included in this review were commonly judged to have a low risk of bias.

2.5.2.2 Limitations

Several limitations of this review were stated. The selection of English language articles published may have introduced bias. Additionally, there are an increasing numbers of studies with positive results that are published in English language journals, which indicates the global spread and acceptance of English language articles. The non-English language studies have been commonly published in local language journals, without the funds for translating their findings into English and hence, the quality of these studies is unknown.[128]

This review was also limited studies to those which were published between 1980 and 2011. The reason was that the prevalence of the conditions of overweight and obesity began to be a health issue from the mid-1980s onwards.

Another drawback of this review was not including the grey literature and conference proceedings, because of the inaccurate or incomplete articles in the electronic bibliographic databases.

If the studies reviewed have shown the secondary or other outcomes, that evidence was not extracted. This was because this review only reflected the scope of weight or BMI change in overweight and obese adults. Thus, the sustainability of other intervention effects was not always known.

A narrative review approach was used to synthesise the included studies. Although 20 studies were included in the review of effectiveness of CWLPs, differences in the interventions such as programme type and duration rendered them inappropriate for meta-analysis.

There were several different weight loss interventions and data were pooled across studies in each of three category conditions based on the intervention components. Also, this review was informed by consideration of the three essential elements which were i) calorie restriction, ii) exercise and iii) support to indicate which CWLPs were superior in achieving weight loss. This was synthesised by following the primary intervention of weight management for three categories of overweight, obesity class I and obesity class II. Therefore, evidence of the effectiveness of CWLPs would be used to support any recommendations to the NHS in order to somewhat reduce health care expenditure, particularly funds employed to counter the effects of being overweight or obese.

2.5.2.3 Generalisability

Although the authors of included studies reported generalisability, only a few studies could be generalised. In this review, generalisability was applicable for popular diets such as WW, SW, RC, Atkins, Zone and Ornish.

Generalisability was considered in terms of study design, study population, particularly for overweight or obese participants, and methods to deliver interventions. To enhance generalisability in terms of methods, maximising the

sample size and using broad inclusion criteria are needed. Special training of support providers is also needed and should be reported in papers.

When considering CWLP in the UK, RC[126] was considered to be the most effective weight loss approach for long-term treatment; however, this intervention did not report generalisability. Intervention in this study consisted of a low-calorie exchange diet (high carbohydrate, protein or fat among three meals), with the option of exercise and support (e.g. role modelling; group, telephone, website and individual support with weekly contact). RC is only offered for UK overweight or obese adults, so other countries that would like to use this programme should develop the programme based on the main elements of RC and should consider which element may not suit their citizens' lifestyles.

Globally, although WW is reported to be the largest worldwide CWLP that includes all three potential weight-loss elements: restriction of calorie level per day, exercise and support, this programme had a wide range of dropout rates, from as low as 16% to as high as 72%. This intervention is able to be generalised to other groups of participants, because in this review, WW is multicentred. This programme is known for being able to produce positive weight change during the long-term treatment.

2.5.3 Comparison with existing systematic reviews

The current systematic review is compared with existing systematic reviews between CWLPs and non-commercial weight loss programmes (NCWLPs).

2.5.3.1 Comparison with commercial weight loss programmes

Tsai and colleagues[116] emphasised only the effectiveness of commercial weight loss programmes and focused on WW and HMRs (Meal Replacement). Comparisons with Tsai and colleagues[116] study will be described in terms of quality of study, the potential elements, effectiveness of programmes and national perspectives.

This present review extracted data by following CONSORT statement of randomised trials of non-pharmacological treatment and assessed the quality of studies by using the risk of bias; however both reviews did no statistical analysis because of the limited comparability of interventions and the quality of data. Using valid and reliable tools contributed to the strength of this current review. Although data extraction in Tsai and colleagues[116] study had no quality assessment,[116] the two systematic reviews are similarly focused on changes in weight. The key elements of CWLP in the present review are presented in terms of diet (total calorie level per day), exercise (daily or optional) and support to potentially enhance the effective weight loss. Tsai and colleagues[116] focused on two types of CWLPs.[116]

The similarities of WW and HMRs programmes, noted in both reviews, are low calorie diet, exercise and support using behaviour weight control methods and weekly group and social support. However, there is a difference in terms of weight change. Weight loss of WW in the present study ranged from 3% at 12 months to 7.3% at six months, whilst these data in Tsai and colleagues[116] study were 5.3% at 26 weeks and 7.5% at 12 weeks.[11, 17, 117, 126, 145, 150-152, 156] Although the maximum change is similar in its effectiveness, the length of treatment is different, as the most effective time for weight loss is between 12 and 24 weeks. It is accepted that WW is

able to achieve the weight loss goal of at least 5% of the initial body weight at 12 weeks.

For HMRs or meal replacement programmes, this present study found 13.7% and 13.9% weight loss at three and six months, whilst Tsai and colleagues[116] study found losses of between 14.1% and 15.3% at 12 weeks. There is a slightly different weight loss because the dropout rate[144, 146] of the study in the current review may cause a lower range of weight loss.

Regarding national perspectives, WW is the only CWLP whose effectiveness has been shown in a large and multicentred RCT in the US.[116] In the UK, WW is also popular CWLP and shows sufficient evidence to be able to generalise for obese adults in the UK.[11, 17, 126, 145, 150-152, 156] Therefore, this WW programme is an important option for the UK population, with all three elements of diet, exercise, support from the group (successful members).

In the UK, similar programmes using very low or low calorie diet are LL[119] and RC.[17, 126] LL and RC programmes also consist of diet, exercise and support through group, telephone and Internet. Although LL is focused on diet and optional exercise, weight loss in this programme is greater than WW, in combination with diet and exercise. This may be as a result of the very low calorie restriction in the LL programme, which allows only 550 kcal/day for energy intake; the greater the calorie restriction in any one day, the greater weight loss at a particular time point. Therefore, in both the US and UK studies LL produced a greater weight loss than WW.

It is clear from this review that CWLPs are effective in helping overweight and obese adults to lose weight. Although studies varied in the type of programmes in terms of diet; exercise; and support including lifestyle modification, not all interventions achieved a weight loss of at least 5% of initial body weight.

In conclusion, after reviewing all included studies, the main body of this review found that the evidence from WW and JC in the US, or LL and RC in the UK, confirmed these particular CWLPs can be recommended to assist people in losing weight, as can meal replacement programmes. CWLPs are provided for participants who are willing to pay for the programme and their resultant health benefits. Furthermore, it would be of interest to guide health care providers not only to assist their patients with weight control but also to advise patients as to which commercial programme may be the most appropriate programme for them, based on available evidence.

2.5.3.2 Comparison to non-commercial weight loss programmes

There are five systematic reviews of non-commercial weight loss programmes (NCWLPs). Loveman and colleagues[161] and Franz and colleague[143] systematically reviewed the effectiveness of weight loss management for the long-term treatment of obesity whilst Avenell and colleagues[162] and Heymsfield and colleagues[163] reviewed the long-term benefits of weight reducing diets in adults. Lastly, Gordon and colleagues[18] focussed on community pharmacy-based weight management services. Findings from the current review will be compared with the five systematic reviews of NCWLPs in terms of quality of study, successful elements, effectiveness of programmes and national perspectives.

With reference to their quality, two reviews[143, 163] included meta-analysis, however, one review[163] used Jadad criteria for assessing quality. Gordon and colleagues[18] assessed studies using a checklist for the Review Body for Interventional Procedures, whilst Avenell and colleagues[162] used their own assessment instrument. Loveman and colleagues[161] used risk of bias, as did this present review. Therefore, all reviews, except Avenell and colleagues,[162] had used previously developed statements to assess the quality of the studies.

Loveman and colleagues[161] only reported the effective weight loss at a 3-year follow-up. To make a comparison with this review time points need to coincide, which in the current review was not be able to do so.

For other systematic reviews, participants' mean weight loss in the present review was greater than Franz and colleague[143] study. The reason was that their findings were a mixture of NCWLP and CWLP. Additionally, their reported mean weight loss was 5% via a diet, whilst mean weight loss in this current review was 7.1% for a diet-based intervention. Diet-based groups in the present review registered greater weight losses than was noted in the study of Franz and colleague[143] but were similar to a study done by Heymsfield and colleagues[163] (7.8%). The reason for the similarity in the findings between this current study and Heymsfield and colleagues[163] study may be calorie restriction in diet programmes. Therefore, consuming a diet incorporating calorie intake restrictions was associated with greater weight loss.

Avenell and colleagues[162] found that low fat diets produced significant weight loss up to three years (-3.55 kg). In this review, mean weight loss in fat restriction was similar to Dansinger and colleague study (-3.3 kg)[11] but slightly less than from Gardner and colleague (-2.6 kg).[117] The reason for the similarity in the findings of three studies may be that there was no specific energy restriction goal in the fat restriction programmes. Therefore, consuming a diet with fat restriction, in combination with an energy restriction goal, was associated with greater weight loss.

Another setting in the community pharmacy-based weight management clinic recently showed mean weight loss ranged from 1.1 to 4.1 kg for 12 months.[18] In this present review, mean weight loss was similar to General Practice (-1.4 kg) but slightly less than from Pharmacy (-2.1 kg)[17] for 12 weeks. Participants who attended in pharmacy in this current review had greater mean weight loss than those in Gordon and colleagues[18] study. This may be related to easier access setting.

Taking into account national perspectives, three studies (Loveman and colleagues,[161] Avenell and colleagues[162] and Gordon and colleagues[18]) were conducted in the UK whilst two remaining reviews[143, 163] were conducted in the US. The effective weight loss of reported in the two US studies was similar to the weight loss reported in the current review, probably due to two thirds of the studies in the current review having been conducted in the US. Therefore, more studies are needed in the UK to determine whether or not the findings from the US can be applied in the UK.

In addition, the NCWLPs have the advantage that they do not involve the payment of fees, although the findings from the systematic reviews suggest they are less

effective in achieving weight loss than CWLPs. The current review has demonstrated that CWLPs can be a good choice for health care providers to advise overweight or obese adults to take up, in order to help them to lose weight. Calorie restriction, exercise and support are the key elements of most weight loss programmes. Therefore, the current systematic review can help policy makers to set up the programmes, which consist of structured interventions (diet and exercise) and various forms of support. Such programmes should be able to demonstrate that they can meet the NICE guidance for weight loss of at least 5% of the initial body weight at three months.

CWLPs appeared to be more effective at producing weight loss than NCWLPs. Overweight or obese people, who are willing to pay for attending these programmes, need to consider whether or not their health benefits of such programmes are superior to NCWLPs.

2.5.4 Implications

Restriction of calorie intake levels per day, exercise and support are potential factors related, to a greater or lesser extent to the achievement of effective weight loss. This helps health care providers to exclusively consider the most effective support for those individuals either wishing or needing to lose weight.

The potential elements in the current review may help policy makers to draw the big picture of weight loss strategy. NHS would focus on the restriction of calorie level per day (energy intake), exercise (energy expenditure) and support methods to energetically assist overweight or obese adults to try losing weight. Additionally,

obesity is related to comorbidity health risks and therefore the greater should be the increase in both physical and psychological health benefits.

The dropout rate in the current review is between 11% and 49%. To decrease the dropout rate, the CWLPs need to provide information on diet and exercise by health care providers or counsellors as well as providing weekly client contacts. Participants should keep daily records of their diet and exercise and have weekly counselling via telephone or Internet. This would, or at least should, encourage overweight or obese adults to achieve weight loss.

This review showed the effectiveness of CWLPs that provide a pattern of three key elements (diet, exercise and support) which are the elements recommended by NICE in their obesity guidelines. The first key element in achieving weight loss is diet where calorie restriction was found to be essential, as opposed to concentrating on the structure of that diet. The second element for successful weight loss is exercise, where a structured programme of exercise is needed which clearly defines the required amounts and types of exercise are defined is needed. The last element is support, where at least weekly contact provided best results. However, adverse events and dropout rates also need to be considered when selecting an appropriate weight loss intervention. Adverse events may reflect a high dropout rate, which is somewhat related to the less effective programme.

2.5.5 Recommendations for further study

The studies in this systematic review lacked evidence of their cost effectiveness and sufficient detail about the support provided. Future studies should consider cost effectiveness of the programme from the viewpoint of the consumer. Future studies should also describe in more detail the support provided so this can be analysed in order to select key elements that could be used in the design of future programmes. Although there were some studies of Internet-based weight loss programmes, more research in this area is needed to determine whether or not such programmes are effective.

2.6 Summary

The three elements of diet, exercise and support commonly underpin the effectiveness of CWLPs, and these programmes can assist overweight and obese adults to lose weight. Most of the evidence in this current review is from US. Therefore, further research is needed in order to investigate the effectiveness of CWLPs in the UK setting.

Chapter 3

Pilot study for a retrospective evaluation of pharmacist-led weight management clinics

This chapter presents the pilot study which tested the proposed data collection method for the main study, as well as testing the prepared database. The quality of the data held in stores was assessed and the data that were used to estimate the sample size needed for the main study will be provided.

3.1 Aim and objectives

This pilot study aimed to test the data collection method and data quality for the evaluation of a pharmacist-led weight management clinic. The objectives were to determine:

1) If it would be possible to measure the effectiveness of Boots Pharmacy Weight Loss Programme (BPWLP).
2) Whether or not clients who participated in this programme achieved their target of at least 5% weight reduction of their initial body weight at six months.
3) The sample size calculation for the main study.

3.2 Methods

3.2.1 Study design

The pilot study was conducted in two Boots pharmacies. Both pharmacies were contacted by Boots staff from Boots Head Office to ask if they would be willing to participate in the research. One of two stores was the first store where the Boots Pharmacy Weight Loss Programme (BPWLP) was launched in 2005. Ethical approval for the pilot study was obtained from Division of Social Research in Medicines and Health, School of Pharmacy, University of Nottingham – see Appendix 6.

The criteria for selecting Customer Record Forms (CRFs) were clients who had been assessed as being suitable for the programme and who had received at least one supply of orlistat.

3.2.2 Study population and sample size

The population of this study represents people who were prepared to pay for a weight management programme. A total of 558 CRFs were held at the two pharmacies for clients who participated in the BPWLP. Sixty CRFs were systematically selected from each Boots pharmacy to give a total of 120 records – see Figure 3.1. The systematic selection of every n^{th} client's paper records at pharmacies was the data gathering method chosen to provide the correct sample size – a one-in-four sample at the first pharmacy and a one-in-six sample at the second. This data were entered into the prepared Access database. The reason for sampling 60 CRFs at each store was guide by a recommendation for pilot studies, that the minimum number should be 30

subjects[164] and to provide sufficient data for the testing planned. A sample of 120 was chosen as the attrition rate from the service was unknown and a sufficient number of clients were needed for analysis at three and six months follow-up points.

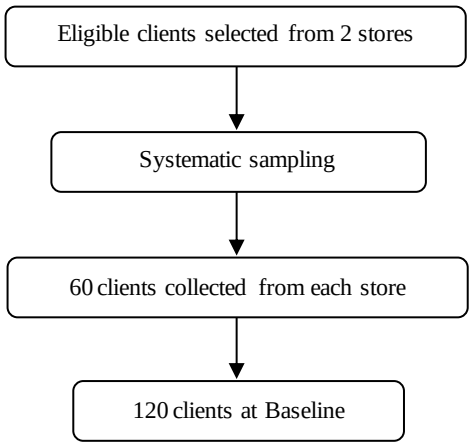

Figure 3.1 Flow chart of data collection for a pilot study

The Access database was designed and informed by following the Customer Record Form (CRF). There were four components to the BPWLP: Customer record form; repeat supply record; consultation checklist; and weight loss chart and customer's consultation notes (Appendix 7). All record forms were hand written by the pharmacists; however, there was one section for the customer to complete (customer's and doctor's details and medicines use).

A prepared Microsoft Office Access database 2007 was generated to store customer records taken from the confidential forms. The database included most items from the record forms. Data not collected were any client identifiers such as name, address and telephone number. At entry to the service, partial date of birth (only year) and postcode (the first part and number from the second e.g. NG7 2) were collected. It

was therefore not possible to identify individual clients from the data collected – see Figure 3.2 to Figure 3.5.

The pilot study was conducted to test the quality of data. Four store-held forms are used for each client. Only three of the four store-held forms were needed for the main study. The consultation checklist (Figure 3.5) was not used because this form is used by the pharmacist to confirm whether or not the procedures of the programme have been followed.

All clients who attended an initial assessment for the BPWLP had their details recorded on a CRF. Pharmacists used this form in checking whether or not clients were suitable for the programme. Therefore, not all clients with a completed CRF were granted entry to the programme and received a supply of orlistat. For this evaluation, only clients who received at least one supply of orlistat were included.

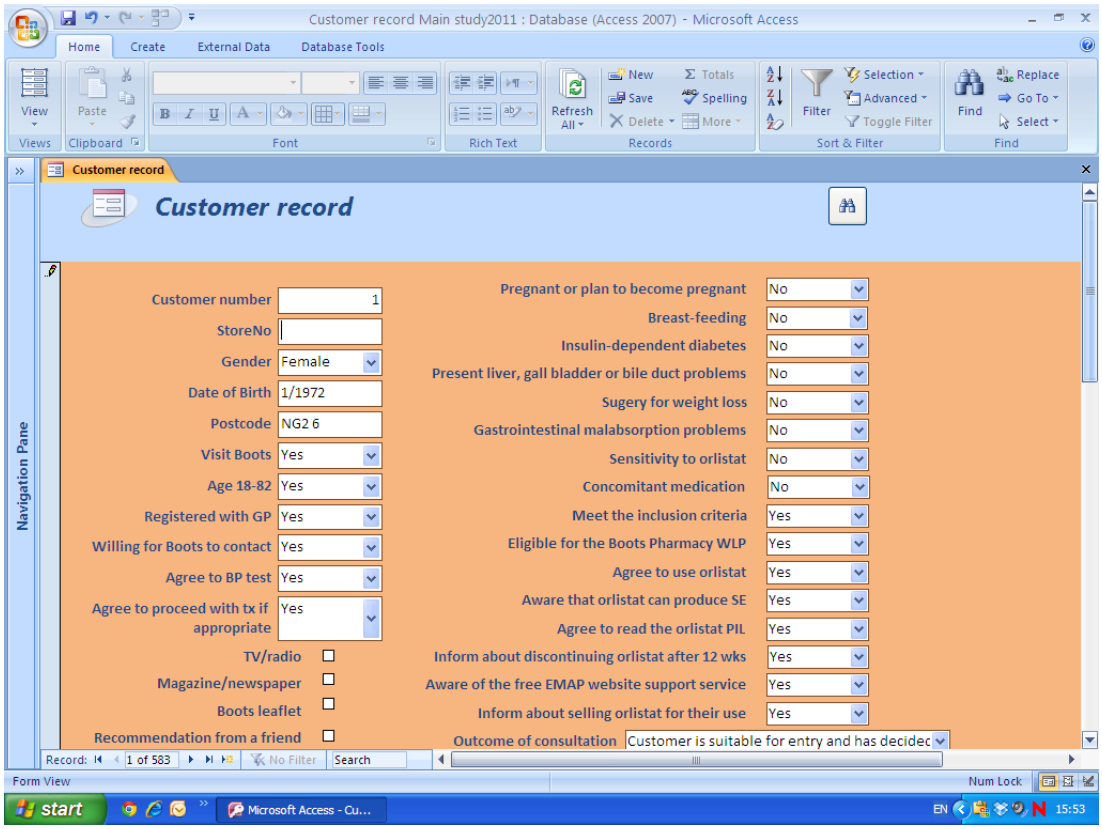

Figure 3.2 Customer Record Form

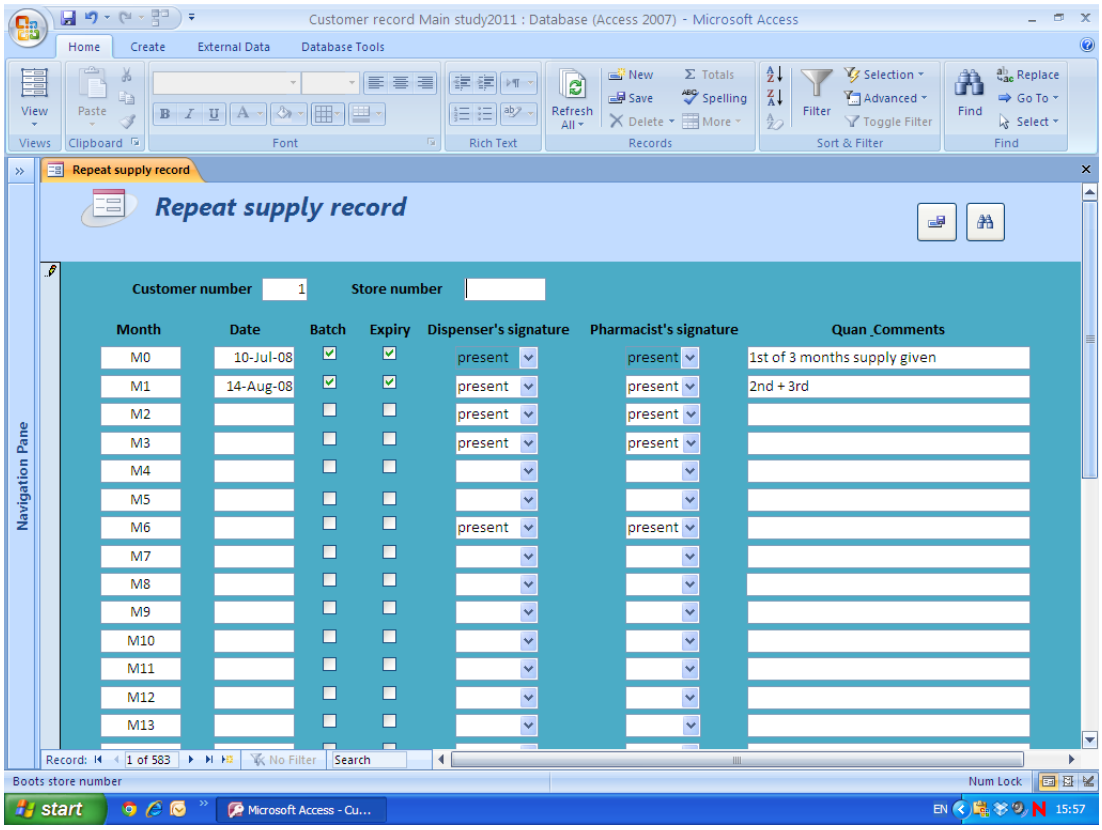

Figure 3.3 Repeat supply record

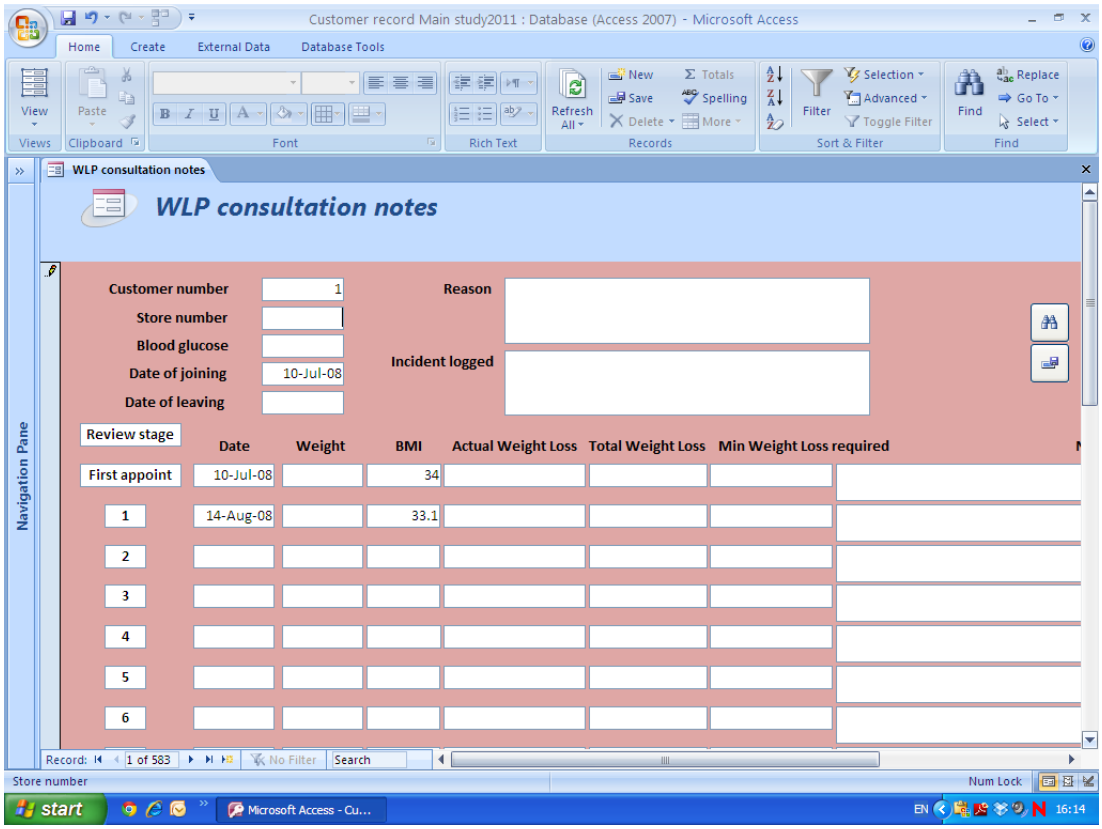

Figure 3.4 Weight loss programme consultation notes

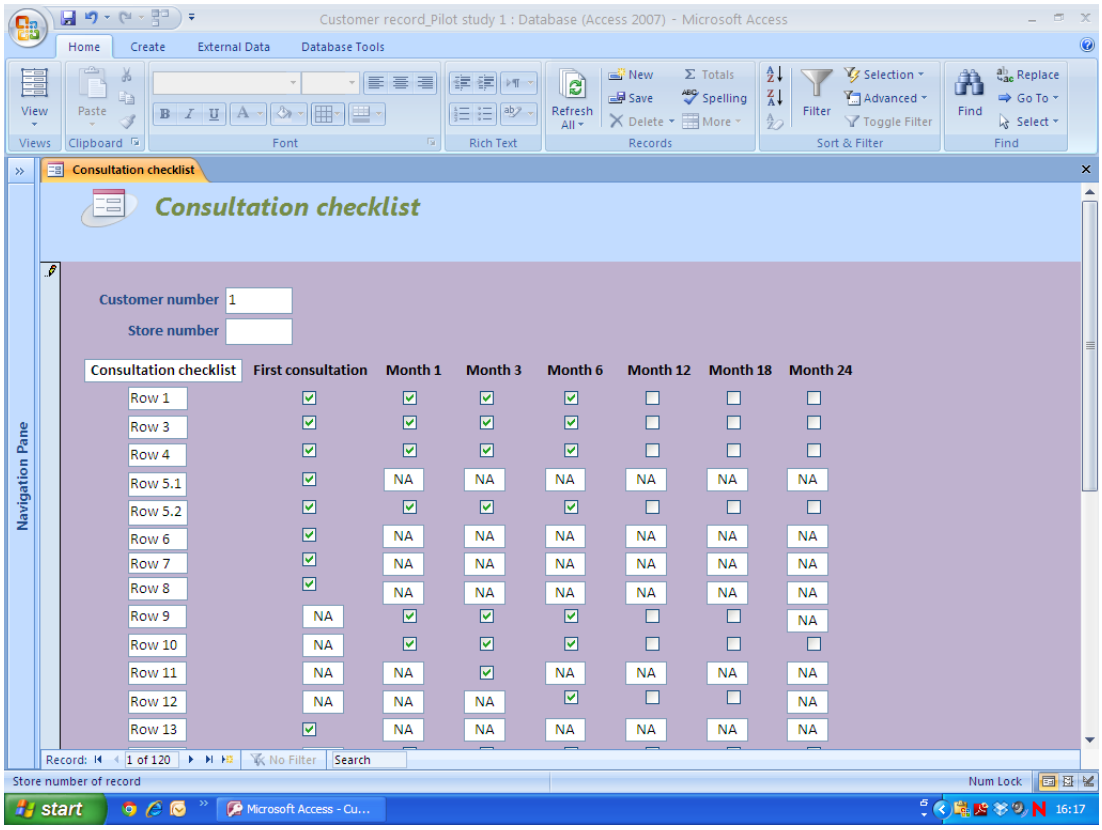

Figure 3.5 Consultation checklist

3.2.3 Data collection

This pilot study was observational and depended on existing records that might be incomplete. Data collection by the main researcher, based on the 120 records at the two stores, took a total of seven days. Key variables collected at baseline, and baseline and follow up are shown in Table 3.1.

Table 3.1 Key variables collected for baseline and follow up (monthly or three monthly)

Baseline	Baseline and Follow up (monthly or three monthly)
- Demographics	- Weight (kg or St & lbs)
- Height (m or ft & inches)	- Body mass index (kg/m^2)
- History information	- Advice given and supply of orlistat
- Inclusion and exclusion criteria	- Side effects experienced
- Blood pressure (BP)	- Dates of visits
- Blood glucose (BG)	- Outcome of the consultation

All available data were entered directly from store-held forms into a prepared database, Figure 3.2 to Figure 3.5. Stores held the forms in an accessible manner so that different forms for each client could be identified.

3.2.4 Data quality

Data were checked for the completion rates for all parts of the forms. The quality of data recorded was rated as ‘acceptable’ where items were recorded in at least 90% of the forms. Where a visit date had been recorded it was assumed that there had been a consultation on that date and therefore the related data should have been present.

3.2.5 Analyses

Data were entered into a prepared Microsoft Office Access database 2007 and transferred to IBM SPSS (Statistical Package for the Social Sciences) V19.0 for analysis. At baseline, continuous variables were expressed as mean ± SD and categorical variables as frequency counts and percentages. Cross tabulations (χ^2) were used to explore differences in the characteristics of clients and to investigate differences across groups in the length of treatment, weight loss (kg) and changes in obesity status classified by BMI. Paired *t*-tests were performed to compare changes in clients' weight and BMI at three months and six months. A *p*-value of < 0.05 was considered to be statistically significant.

3.2.5.1 Testing normal distribution

The reason for using a paired *t*-test was that both parameters of weight and BMI were normally distributed as tested by Kolmogorov-Smirnov, and two other common procedures, which were graphical methods (histogram, a curve pattern in the corresponding Q-Q plot and detrended normal Q-Q plots) and numeric methods (skewness and kurtosis indices).

3.2.5.2 Sample size calculation for the main study

Data from this pilot study was used to estimate the minimum sample size calculation for the larger study of the effectiveness of the weight loss service using mean weight loss (± SD).

3.3 Results

3.3.1 Number of cases per day

Similar numbers of cases were able to be collected during the day in each store – a mean of 18 and 20 per day in the two stores.

3.3.2 Completion rates

Completion rates for data recorded in the customer record forms (CRFs) varied from 90% to 100%; almost 65% of variables had a 100% completion rate – see Table 3.2. The key variables of importance to this study were well completed, particularly at baseline. Blood glucose was less well completed at baseline with 93% of clients having this measure recorded. Dates of visit and weight at the 3-month visit were also less well recorded, with 92% of clients having a record for both.

Table 3.2 Quality of data recording in store by variables

Variables	Records with complete number	%
Gender	120	100
Age	119	99.2
Height (metres)	120	100
Weight (kg)		
Baseline	120	100
3 months	110	91.7
6 months	46	100
BMI (kg/m^2)	120	100
Date of visits		
Baseline	120	100
3 months	110	91.7
6 months	46	100
BP recorded		
Systolic blood pressure (SBP)	118	98.3
Diastolic blood pressure (DBP)	118	98.3
Random blood glucose recorded	112	93.3
Minimum weight loss required at 3 months (kg)	119	99.2
Other variables at the initial visit		
Postcode	119	99.2
Target weight: Weight loss required at 3 months (kg/lbs)	119	99.2
History information		
Doctor's details	120	100
Any medicines currently used	119	99.2
Inclusion criteria		
BMI equal or greater than 30 kg/m^2	120	100
BMI equal or greater than 28 30 kg/m^2 with one co-morbid health risk	120	100
Meet the inclusion criteria	119	99.2

Table 3.2 (continued)

Variables	Records with complete number	%
Eligible for the BPWLP: Exclusion criteria: 8 items[a]	117	97.5
Advice given: 6 items[b]	120	100
Orlistat supply: 9 items[c]	120	100
Other variables at subsequent visits		
Side effects experienced	120	100
BP > 140/90 mmHg: Systolic and diastolic	8	6.7
BG > 5.6 mmol/L	-	-

[a] 8 items = 1. Pregnant, 2. Breast-feeding, 3. Insulin-dependent diabetes, 4. Any present liver; gall bladder or jaundice, 5. Surgery for weight loss, 6. Gastrointestinal malabsorption problems, 7. Sensitivity to orlistat and 8. Any concomitant medication such as amiodarone, acarbose or ciclosporin

[b] 6 items = 1. Agree to use orlistat, 2. Aware that orlistat can produce side-effects, 3. Agree to read the orlistat Patient Information Leaflet (PIL), 4. Inform about discontinuing orlistat after 12 weeks is inadequate, 5. Aware of the free Electronic-Motivation, Advice and Pro-active (EMAP) website support service and 6. Inform about selling orlistat for their use

[c] 9 items = 1. Outcome of consultation, 2. Your steps to successful weight loss leaflet, 3. Patient's guide, 4. Orlistat 120 mg capsules (84 capsules/pack), 5. Final check by pharmacist, 6. Quantity, 7. Batch, 8. Expiry and 9. Comments (Yes/No)

3.3.3 Demographics

Records for 120 clients, who were suitable for the BPWLP and who had received at least one supply of orlistat, were selected. Follow-up data were available for clients attending the programme for up to 20 months.

Most clients were women (91%) aged 40-59 years. Almost three quarters of clients were taking prescribed or purchased medicines for other conditions and most had not used the programme previously – see Table 3.3.

Clients' mean weight at baseline was 93 kg and mean BMI was 35 kg/m^2. Mean baseline blood pressure and blood glucose were within the normal ranges. Clients were required to give their minimum weight loss goal (4.7 ± 0.9 kg) for the first three months.

Over 80% of clients had a BMI greater than 30 kg/m^2 at baseline and opted to pay for three months of orlistat supply (rather than the more expensive pay monthly option). Less than half of clients (n = 51, 42.5%) continued on the programme longer than three months – see Table 3.3.

Table 3.3 Client demographics at baseline (n = 120)

Characteristics	Number of clients or Mean ± SD	% or range
Client's details		
Gender		
Female	109	90.8
Male	11	9.2
Age at entry to programme, years (n = 119)*		
18-29	11	9.2
30-39	13	11.0
40-49	35	29.4
50-59	42	35.3
60 and older	18	15.1
Currently taking any medicines prescribed or purchased		
Yes	87	72.5
No	33	27.5
Number of medicines prescribed or purchased		
No medicine	33	27.5
1 medicine	32	26.7
2 medicines	17	14.2
3 medicines	19	15.8
4 or more medicines	19	15.8
Previous BPWLP		
- No	62	51.7
- Yes	8	6.7
- Did not report	50	41.7
Client's biometrics		
Height, metres	1.63 ± 0.8	1.42-1.84
Weight, kg	92.9 ± 16.9	60.0-151.8
Baseline BMI, kg/m^2	34.8 ± 5.1	28.3-57.9
Blood pressure (range), mmHg (n = 118)*		
- Systolic blood pressure	130.8 ± 16.0	95-178
- Diastolic blood pressure	85.6 ± 11.0	62-113

*This groupings do not total 120 due to missing data.

Table 3.3 (continued)

Characteristics	Number of clients or Mean ± SD	% or range
Client's biometrics		
Blood glucose (range), mmol/L (n = 112)*	5.6 ± 1.8 (3.1-18.9)	2.6-18.5
Minimum weight loss required at 3 months, kg (n = 119)*	4.7 ± 0.9	2.7-7.7
Other details		
Pharmacist's checklist for inclusion criteria		
Inclusion criteria**		
BMI ≥ 30 kg/m^2	100	83.0
BMI ≥ 28 kg/m^2 with at least one co-morbid health risk	20	17.0
Oristat supply***		
3-month option	102	85.0
1-month option	18	15.0
The length of treatment in months (range)	4.5 ± 3.5	1-20
- Up to 2 months	33	27.5
- 3 months	36	30.0
- 4-6 months	24	20.0
- More than 6 months	27	22.5

*This groupings do not total 120 due to missing data.

**This BMI is the inclusion criteria for participating in this programme.

***3-month option is a supply of 3x84 orlistat 120 mg capsules. 1-month option is a supply of 84 orlistat 120 mg capsules

3.3.4 Study outcomes

3.3.4.1 Testing normal distribution

Graphical interpretation and the values of skewness and kurtosis could help to assess normality. Although both skewness and kurtosis are zero in a normal distribution, their values were 0.78 and 0.77 in weight and 1.4 and 3.0 in BMI, respectively; the farther away from zero, the more non-normal the distribution. Although the distribution of weight was moderately skewed, and the BMI data was highly skewed,

it could be acceptable for normal distribution by testing formal normality – see Appendix 8 and Table 3.4.

Testing normality with significant value from the results of the Kolmogorov-Smirnov statistic indicated a *p*-value greater than 0.05, which defines as a normal distribution. The *p*-value of weight and BMI data set was larger than 0.05. Therefore, both mean weight and mean BMI at baseline were normally distributed.

Table 3.4 Tests of normality for both weight and BMI

Tests of normality	Weight (kg)	BMI (kg/m^2)
Skewness*	0.78	1.4
Kurtosis**	0.77	3.0
Kolmogorov-Smirnov (Sig.)***	0.22	0.11

*The skewness value provides the asymmetrical distribution either positive (skew to the right) or negative (skew to the left) skewed.[165, 166] If the distribution is normal, skewness value is zero or between -2 and +2.

**Kurtosis provides the peakedness of the distribution. If the distribution is normal, kurtosis value is 3 (exactly 0).[165]

****p*-value < 0.05 considered statistically significant.

3.3.4.2 Clients' weight and BMI

Most clients lost up to 3 kg in the first month and at three months had lost more weight; 69% met the criteria at month 3 – see Table 3.5. Using a paired *t*-test to compare mean weight and mean BMI – see Table 3.6, there were statistically significant differences from baseline at both three and six months ($p < 0.001$). About four-fifths (78%) of clients remaining in the programme achieved their weight loss at three months.

Table 3.5 Weight change over time for clients attending BPWLP (n = 120)

	Change from baseline		
	Month 1 (n = 116)	Month 3 (n = 111)	Month 6 (n = 46)
Mean weight change (kg) ± SD	2.7 ± 1.9	4.9 ± 2.4	8.0 ± 3.7
Number of clients (%) in each weight change category			
- Gain	7 (6.0)	1 (0.9)	2 (4.3)
- No change	1 (0.9)	-	-
Loss of			
0.1-0.9 kg	10 (8.6)	3 (2.7)	-
1-2.9 kg	47 (40.5)	20 (18.0)	2 (4.3)
3-4.9 kg	35 (30.2)	33 (29.7)	2 (4.3)
5-7.9 kg	16 (13.8)	44 (39.6)	17 (37.0)
8-10.9 kg	-	8 (7.2)	12 (26.1)
11-13.9 kg	-	2 (1.8)	11 (23.9)

Table 3.6 Weight and BMI change at 3-month and 6-month visits compared with baseline

	Time		
	Baseline (n = 116)	3-month (n = 111)	6-month (n = 46)
Weight (kg)			
Mean weight (± SD)	93.0 ± 16.8	88.6 ± 16.5	85.1 ± 13.8
Mean weight change from baseline (± SD)	-	4.9 ± 2.4	7.9 ± 3.7
Comparison with baseline (Paired t-test)	-	$t = 22.2$, $p < 0.001$	$t = 15.6$, $p < 0.001$
BMI (kg/m^2)			
Mean BMI (kg/m^2) ± SD	34.8 ± 5.1	33.1 ± 5.1	31.9 ± 4.2
Mean change in BMI from baseline (± SD)	-	1.8 ± 1.0	3.0 ± 1.5
Comparison with baseline (Paired t-test)	-	$t = 18.4$, $p < 0.001$	$t = 13.9$, $p < 0.001$

Differences in baseline characteristics were compared for those who remained in the programme less than three months (n = 69) with those remaining for three months or more (n = 51).

There were no significant differences in the baseline characteristics of clients who remained in the programme for up to and more than three months in terms of gender (χ^2 = 0.18, p = 0.67), age (χ^2 = 1.21, p = 0.89), geographical area (χ^2 = 0.69, p = 0.71), previous experience of BPWLP (χ^2 = 1.59, p = 0.45), number of other medicines taken (χ^2 = 1.90, p = 0.93) and BMI (χ^2 = 2.42, p = 0.49) – see Table 3.7.

Table 3.7 Baseline characteristics of clients who remained in the programme less than 3 months and at least 3 months (n = 120)

Characteristics	No of clients in the programme (%)		
	Up to 3 months n = 69	> 3 months n = 51	χ^2, *p*-value*
Sex			
- Female	62 (89.8)	47 (92.2)	0.18, 0.67
- Male	7 (10.2)	4 (7.8)	
Age (years), n = 119**			
- 18-29	8 (11.6)	3 (6.0)	1.21, 0.89
- 30-39	8 (11.6)	5 (10.0)	
- 40-49	21 (30.4)	14 (28.0)	
- 50-59	22 (31.9)	20 (40.0)	
- 60-69	9 (13.0)	7 (14.0)	
- 70+	1 (1.4)	1 (2.0)	
Geographical area, n = 119**			
- No record found	2 (2.9)	2 (3.9)	0.69, 0.71
- Deprived area	11 (16.2)	11 (21.6)	
- Affluent area	55 (80.9)	38 (74.5)	
Previous experience of BPWLP			
- No	33 (47.2)	29 (56.9)	1.59, 0.45
- Yes	6 (8.7)	2 (3.9)	
- Question not on the form	30 (43.5)	20 (39.2)	
Number of other medicines taken			
- No medicine	20 (29.0)	13 (25.5)	1.90, 0.93
- 1 medicine	19 (27.5)	13 (25.5)	
- 2 medicines	8 (11.6)	9 (17.6)	
- 3 medicines	12 (17.4)	7 (13.7)	
- 4 or more medicines	10 (14.5)	9 (17.6)	

*p-value < 0.05 considered statistically significant.

**This groupings do not total 120 due to missing data. Geographical area was categorised, based on clients' partial postcode, into three groups: affluent and deprived areas, and no record found.

Table 3.7 (continued)

Characteristics	No of clients in the programme (%)		
	Up to 3 months n = 69	> 3 months n = 51	χ^2, *p*-value*
BMI (kg/m^2)			
- 28.0-29.9	10 (14.5)	10 (19.6)	2.42, 0.49
- 30.0-34.9	32 (46.4)	16 (31.4)	
- 35.0-39.9	18 (26.1)	19 (37.3)	
- ≥40	9 (13.0)	6 (11.8)	
Blood pressure (mmHg), n = 118**	67 (100.0)	51 (100.0)	-
Blood glucose (mmol/L), n = 112**	64 (100.0)	48 (100.0)	-

*p-value < 0.05 considered statistically significant.

**This groupings do not total 120 due to missing data.

3.3.4.3 Clients' health risks

More than three quarters of clients had no co-morbid health risks. The most frequent co-morbid health risks were high blood pressure, osteoarthritis and high cholesterol – see Table 3.8.

Table 3.8 Clients with BMI < 30 kg/m^2 and their co-morbid health risks (n = 20)

28 kg/m^2 ≤ BMI < 30 kg/m^2 with one co-morbid health risk	Number	%
Number of co-morbid health risk		
No co-morbid	100	83.4
One co-morbid	10	8.3
Two co-morbid	10	8.3
Co-morbid health risk*		
High blood pressure (HBP)	9	7.5
Osteoarthritis of a weight-bearing joint (e.g. knee, spine or hip)	5	4.2
Raised cholesterol	4	3.3
Any respiratory disease (e.g. asthma)	3	2.5
Non insulin dependent diabetes (NIDDM)	1	0.8
Heart disease	1	0.8
Others e.g. back or knee pain or knee joint problems	11	9.2

*Many clients had more than one co-morbid health risk which came from the selected list in CRFs.

3.3.4.4 Clients' participation in the BPWLP

Using the dates recorded in clients' records, 97% (n = 116/120) returned for their follow-up visit at one month, 93% (n = 111/120) at three months and 38% (n = 46/120) returned for six month follow-up visits – see Appendix 9 and Table 3.9.

Table 3.9 Number and percent of clients who attended and did not attend in the programme follow-up visits (n = 120)

Particular time at follow-up visits	Month 1 (%)	Month 3 (%)	Month 6 (%)
Attended	116 (97)	111 (93)	46 (38)
Continued	115 (96)	98 (82)	27 (22)
Left programme	1 (1)	9 (11)	14 (16)
Did not attend	4 (3)	4 (7)	5 (62)

During the follow-up visits, most clients were supplied with orlistat 97% (n = 116), 78% (n = 94) and 34% (n = 41) at month one, three and six, respectively – see Appendix 9.

3.3.4.5 Clients' consultation notes

The consultation notes in BPWLP were classified into three themes: positive, neutral (absence of problems) and problem notes. The positive notes included comments such as (very) happy/pleased/motivated, achieved/met target, brilliant/well, good/ok/fine or encouraged. The neutral, or absence of problems, notes included no change in medical condition/medication change, no side-effects, no problem, no treatment effects and no contraindication. Problem notes included comments relating to disappointment in rate or quantity of weight loss (e.g. slow loss, not achieved/happy) or reports of side-effects (e.g. constipation, diarrhoea).

Most clients had positive notes (n = 99, 82.5%) and neutral notes (n = 79, 65.8%) in their consultation notes. Around one third (n = 42, 35%) had problem notes in their consultation records, with only three clients having no notes. Many clients had a mixture of comments in their notes with 16% having all three types (positive, neutral and negative) of comments in their records – see Table 3.10.

Table 3.10 Consultation notes recorded (n = 120)

Consultation notes	Number of clients*	%
Positive and neutral notes	46	28.3
Positive and problem notes	15	12.5
Neutral and problem notes	4	3.3
Positive notes	19	15.8
Neutral or absence of problems	10	8.3
Problem notes	4	3.3
No comment in notes	3	2.5
All positive, neutral and problem notes	19	15.8

*Many clients had more than one comment in their records.

Regarding the problem notes, any report of side-effects related to orlistat was found in the notes for eight clients (6.8%). Half of these side-effects were reported as constipation and half were diarrhoea.

3.4 Discussion

3.4.1 Main findings

The objective of this pilot study was to test the data collection method and data quality for a wider evaluation of a pharmacist-led weight management programme. In terms of the method for collecting data, around 20 cases per day were able to be recorded. This number was used to determine the minimum number of clients that a store should have, in order to be selected for the main study. The number 20, in relationship to cases per day, was arbitrarily defined to make the data collection process more time efficient.

Completion rates for key variables were generally very good with the majority being over 95% but some were less well recorded. Notably, blood pressure and blood glucose at follow-up visits were rarely recorded, with only 7% of clients having a blood glucose measurement other than at baseline, because recording the variables of blood pressure and blood glucose was not a mandatory component of the programme. Therefore, it will not be possible to determine the effects of the programme on clients' blood pressure and blood glucose in the main study.

The basic planned analyses were tested with the pilot study to ensure that the data gathered would be of sufficient quality and availability to perform the analyses.

The primary objective of the main study was initially planned to determine the effectiveness of BPWLP, whether or not clients who participated in this programme achieved a weight reduction at six months. However, the pilot study has shown that less than one-third of clients remained in the programme at six months. As a consequence, the timing of the primary end point of the study needed to be reconsidered and this low number of clients means it may be difficult to make any conclusions about longer term effects of the programme.

The mean reduction in weight for completers at three and six months was 4.9 kg and 7.9 kg, whilst mean BMI at those time points was 33.0 kg/m^2 and 31.7 kg/m^2, respectively. Mean weight loss at three months could be used to help calculate the sample size for a larger study of the effectiveness of the pharmacist-led weight management service.

In addition, compared to a community-based weight loss programme of the same duration, at three months[167] mean weight losses were approximately 3 kg, whereas this CWLP at three and six months had mean weight losses ranging from 4 kg to 7 kg. These data are similar to when compared with the studies of Graham et al.[168] and Van Gaal et al.[169] however, at six months, this pilot study showed greater reduction in weight (5.0 kg) than both studies.[168, 169] On the other hand, to compare with Kaya et al.[75] study at three months, this pilot study showed a smaller mean weight loss and BMI decrease than Kaya et al.[75] who reported a mean weight loss of 9.3 kg and mean BMI reduction of 3.6 kg/m^2.

3.4.2 General discussion

The majority of clients in the programme were females aged between 40 and 59 years. All clients met the inclusion criteria for the programme. Most clients remained in the programme for up to three months. The researcher had initially anticipated that six months might be a suitable primary outcome measure but in the light of the pilot data this needs to be reconsidered. Also due to low numbers of clients it may be difficult to make any conclusions about longer term effects of the programme. A previous study has examined efficacy and tolerability of orlistat for 6-month treatment period in 124 obese men and women with mean weight loss 9.8%.[169]

This pilot study evaluated the effectiveness of the pharmacist-led weight management clinic at Boots Pharmacy. About three quarters (78%) of clients remaining in the programme achieved meaningful weight loss at three months (≥ 5% of initial body weight) as a part of the pharmacist-led weight management programme. This pilot study showed a greater a proportion of participants achieving

this meaningful weight loss than a previous study where 32% achieved at least 5% weight loss after 12 weeks.[170]

The mean reduction in weight for clients who completed follow-up at three and six months was 4.9 ± 2.4 kg and 7.9 ± 3.7 kg, respectively. Additionally, clients' BMI diminished to 33.0 ± 5.0 kg/m^2 and 31.7 ± 4.2 kg/m^2 during the same period of treatment, respectively. Similarly, mean BMI in another study was ranging from 30 kg/m2 to 34.9 kg/m2 in a category of obesity class I.[167] Furthermore, clients mostly stayed in the programme for up to three months.

Clients who were attending the BPWLP had low obesity-related health risks with only one quarter of the total clients reporting having these. In this pilot study, the most common co-morbid health risks were high blood pressure, osteoarthritis and high cholesterol. The previous literatures showed slight differences in the most frequent co-morbid health risks associated with obesity, which were coronary heart disease, type 2 diabetes mellitus and high blood pressure.[29] However, co-morbid health risks in this study were inferred from the client checklist, which was completed based upon questions from the pharmacist, and had a little detail. Other reasons for fewer co-morbid health risks may be the nature of the Boots programme, and clients may have been healthier than those in some of the other studies cited. Therefore, information concerning clients' co-morbid health risks could only be based upon what was included on the forms.

For clients' participation in the BPWLP, less than half of the clients returned for their follow-up visit at six months. As a result, the primary outcome for the main study will change from weight loss at six months to weight loss at three months.

The evaluation of consultation notes showed 6.8% of clients reported side-effects from the service. This rate of side-effects differs from that found in other studies, where the levels of those experiencing side-effects were 48% and 67%.[75, 168] The consultation notes only contain what pharmacists chose to record and therefore it is not known whether these reflect the true level of occurrence of side-effects. However, pharmacists also had an electronic record for their clients if any clients ever came in for anything else. Therefore, the record of side-effects on the CRFs was the low percentage.

3.4.3 Strengths

The Boots Pharmacy Weight Loss Programme is a commercial weight loss programme led by pharmacists using orlistat in combination with a restricted diet and exercise.

A prepared database was supportive for collecting data from store held forms. It was accessible to directly collect CRFs for each client. Clients were selected by systematic random sampling because this sampling method led to a further spread of the sample across the form population.[171]

This pilot study has enabled the researcher to assess the quality of the data. Regarding results, completion rates for all parts of the forms were generally very good with the majority being over 90%, which was within the expected range.

The pilot study ensured that there was sufficient quality and available information for testing and performing the analyses. This confirmed that it is possible to measure the effectiveness of Boots Pharmacy Weight Loss Programme (BPWLP) for clients who attended this programme and achieved the target of at least 5% weight reduction of their initial body weight at three months. As a result, this pilot study has provided estimates for the main study sample size calculation, using mean weight loss (kg) and standard deviation (SD).

3.4.4 Limitations

The limitations of this pilot study were primarily before and after study design. Only one group of clients who attended was willing to pay for the BPWLP; therefore, this would limit the study design. Another limitation was the major loss to follow-up. The dropout rate will affect the evaluation of the effectiveness of this particular commercial weight loss programme. Lastly, there was the potential bias in using unblinded recording of information. This would be affected by organisational constraints; therefore, data for the main study will be selected from multiple types of Boots pharmacies.

3.4.5 Refinements for the main study

As a result of this pilot study a number of refinements will be made to the main study. In particular the researcher will be obliged to reconsider the time frame for the primary outcome and also the fact that the researcher will not be able to investigate changes in blood pressure or blood glucose during the programme, due to a lack of follow-up data.

3.5 Summary

The pilot study showed the feasibility of evaluating the effectiveness of a pharmacist-led weight management clinic. The data recording was generally of a very high quality with completion rates in the data records for the key variables being higher than 90%. The lower than anticipated rates of participation in the programme beyond three months means that the primary outcome will need to change from weight loss at six months to three months and that consequently it will not be possible to investigate the longer term effects of the programme.

Chapter 4

Retrospective evaluation of a pharmacist-led weight management clinic

This chapter describes a retrospective evaluation of a pharmacist-led weight management clinic conducted in Boots pharmacies. This record review of the Boots Pharmacy Weight Loss Programme (BPWLP) investigated the effectiveness of the service in assisting clients to lose weight.

4.1 Aim and objectives

The aim of this study was to evaluate the effectiveness of a pharmacist-led weight management clinic in achieving weight loss for obese clients through the prescription of orlistat, in combination with diet, exercise and advice.

The primary outcome of the study was to achieve a change in body weight of at least 5% of the initial body weight at three months.

The objectives of the study were to:

- Describe the characteristics of clients who participated in the weight loss programme in terms of:
    - The length of time clients remained in the programme
    - The rate of unwanted effects based on the consultation notes
    - Reasons for drop-out from the programme
- Determine the effect of orlistat 120 mg on body weight and BMI at three months for clients participating in the programme
- Determine any associations between clients' biometric data at the initial visit and:
    - Gender: female and male
    - Age: younger than 50 years and 50 years and older
    - Time period in the programme: up to three months and more than three months
- Determine characteristics associated with:
    - Weight reduction at three months
    - Clients who achieved at least 5% weight loss from their initial weight

4.2 Methods

4.2.1 Study design

Data were collected using Customer Record Forms (CRFs) and customer consultation notes from a programme run by a commercial weight management clinic. A retrospective record analysis was performed.

An agreement about the study was made between the University of Nottingham, Boots UK Limited and SS (PhD research student) – see Appendix 10. This agreement was drafted by Boots UK (Dr Tracey Thornley and Julie Hanmer, Industrial Supervisors), the University (Cheryl Ruse, Contracts Officer) and by the academic supervisors (HB and AA). The agreement described the project's aim, the primary outcomes, the included records for data collection and data analysis. SS was not permitted to directly access the CRFs held in Boots pharmacies. In order to meet the requirements of the Data Protection Act of 1998,[172] details of clients' names and addresses were not recorded. The clients were assigned a unique study number so that the individual part of their store records could be linked whilst ensuring data confidentiality.

4.2.2 Study population

In 2011, the BPWLP was available in 205 Boots pharmacies in England and Wales, of which 22 are located in the East Midlands area. For convenience, pharmacies in the East Midlands were selected as potential study sites to save time and money in data collection. Boots Head Office provided data about the number of clients who had used the services between January 2006 and January 2009.

Stores included in the study had a minimum of 20 clients who had participated in the programme; therefore 20 of the 22 stores were suitable for inclusion in the study.
The pharmacies were grouped into high street pharmacies – large stores and other pharmacies which included small stores, health centres and edge of town pharmacies. Five pharmacies in each group were then randomly selected using SPSS.

Each of the pharmacies was contacted by a member of staff at Boots head office to ask if they were willing to participate in the study. If a pharmacy declined to participate in the study, a further random sample from the same type of pharmacies was taken in order to select another pharmacy as a replacement. At the first contact, five large high street and three other pharmacies agreed to participate. Therefore, two other pharmacies were randomly selected from the remaining stores, and they agreed to participate in the study – see Figure 4.1.

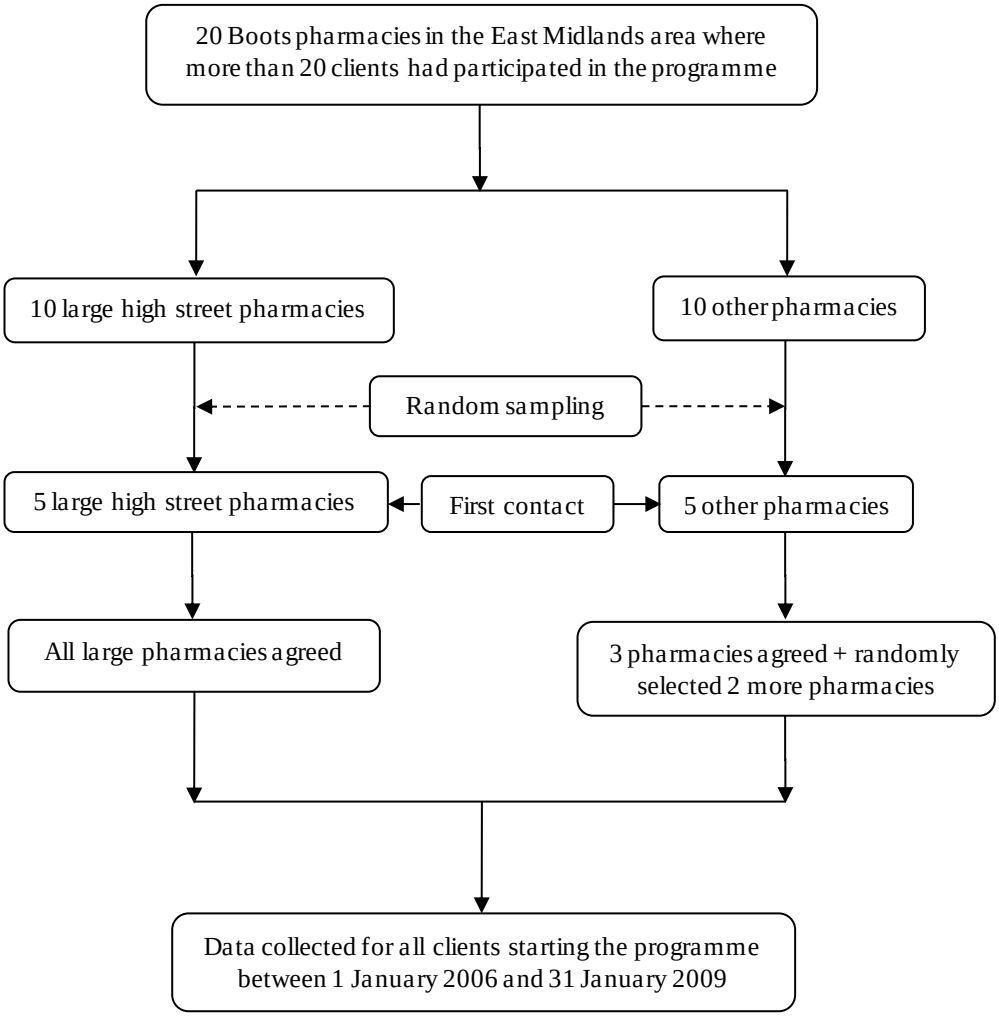

Figure 4.1 Summary of steps for collecting data

Data collectors were recruited from undergraduate and postgraduate students from the University of Nottingham who were employed part time at Boots. They visited the pharmacies and photographed the records of all the clients who had started the programme between 1 January 2006 and 31 January 2009. To ensure confidentiality, *post-it* notes were used to cover personal details of clients (name, address and partial date of birth) for the photographs, revealing only partial postcode (the first part of the postcode) and year of birth.

The inclusion criteria for clients in the study were:

- that they had received at least one supply of orlistat
- that their initial visit was over two years before the data collection date, that is, prior to 31 January 2009 (to allow for them to complete the maximum two years in the programme)

The inclusion criteria for clients' body mass index (BMI) in the BPWLP were:

- Equal to or greater than 30 kg/m^2
- Equal to or greater than 28 kg/m^2 with at least one risk factor such as:
    - Non insulin dependent diabetes
    - Raised cholesterol
    - Stress incontinence
    - Any heart disease
    - Hiatus Hernia
    - Awaiting surgery
    - High blood pressure
    - Pituitary disease

- Gallstones
- Gastro-Oesophageal Reflux disease (GORD)
- Any respiratory disease (e.g. asthma, COPD, sleep apnoea)
- Osteoarthritis of a weight-bearing joint (e.g. knee, spine or hip)

The exclusion criteria for clients in the BPWLP were:

- Being pregnant or breast-feeding
- Having the following health conditions:
  - Insulin-dependent diabetes
  - Liver disease
  - Gall bladder or bile duct problems which result in Cholestasis (jaundice)
  - Surgery for weight loss
  - Gastrointestinal malabsorption problems
  - Sensitivity to orlistat
  - Taking the following medicines: amiodarone, acarbose or ciclosporin

In this study the internationally recognised classification for BMI[3] was used. A BMI that is elevated to 30 kg/m^2 or more is defined as obese; overweight was classified as having a BMI of 25.0-29.9 kg/m^2. Obesity class I included clients with a BMI of 30.0-34.9 kg/m^2, class II was defined as a BMI of 35.0-39.9 kg/m^2, and class III was defined as a BMI of 40 kg/m^2 or greater.[3, 24]

4.2.3 Sample size calculation

The sample size of CRFs was determined based on 1) the need for sufficient numbers from each cluster size (pharmacy) and 2) power calculations to detect differences between baseline (before) and follow-up (after) within the Boots Pharmacy Weight Loss Programme.

Data from the pilot study was used to determine the minimum required sample size. The pilot study found there had been a mean weight loss of 4.9 kg (SD = ±2.4) for the 120 clients at three months.

Rather than taking a sample from each pharmacy, a random selection of pharmacies was chosen. The sampled population was drawn from 10 Boots pharmacies. It was assumed that clients within a selected pharmacy may be more similar than clients from different stores, due in part to similar socioeconomic characteristics, for example.

Differences in body weight (kg) were being compared at baseline (before the start of the programme) and at three months (after being in the programme for three months), thus there was only one group of clients. A one-sample test was needed, which would challenge the null hypothesis that the mean of individual differences in body weight was zero: that is programme had no effect on body weight. If the effectiveness of this programme was the same as the pilot result, a mean difference of -4.9 kg in body weight would be seen. A sample size calculator[173] was used to determine the number of clients needed, using a power of 95% two-sided and alpha =

0.05.

This study considered weight changes of at least 5% of the initial weight at three months as the primary endpoint, and the length of time clients remained in the weight loss programme, the rate of unwanted effects and change in BMI as secondary endpoints.

It was calculated at 95% power (at the two-side error 5.0% level) to detect a difference of 4.9 kg in body weight, 256 clients would be needed as the initial number. To compensate for expected client drop-out before three months (an 8% of drop-out rate was indicated in the pilot study), 384 clients were selected as the minimum number of clients' records that needed to be collected.

4.2.4 Data collection

Data were collected for all clients who participated in the programme from January 2006 to January 2009. The data collected from the three different store held forms were (Appendix 7):

- Demographics e.g. gender, year of birth, the first four digits of postcode
- Biometric data: weight (kg), height (cm), body mass index (kg/m^2), blood pressure, blood glucose
- History information: customer's details, doctor's details, any medicines taken, previous weight loss attempts
- Detail of whether or not clients met programme inclusion and exclusion criteria

- Records of advice given and supply of orlistat by the pharmacist
- Side effects reported to the pharmacist
- Dates of visits to the programme
- Additional notes of pharmacists' consultations

All records were hand written, clients completed their personal details, and the pharmacist completed the rest of CRF. Photographs of the forms were downloaded to a computer with password protection. Data collectors (Appendix 10) checked the photos at the pharmacies to ensure they were readable and if not retook them prior to leaving the store. Unfortunately, a few records were still unreadable because of the handwriting. If the photographs were unclear, at least two pharmacists, who were independent, were asked to read the handwriting; if the checkers agreed that they had been able to interpret the handwriting, the data were included but where there was no agreement about what had been written the data were treated as missing data. Data were subsequently entered into a prepared Microsoft Office Access database 2007 database.

For the clients' initial BPWLP visit, the pharmacist recorded data about the client including gender, age, weight (kg or lbs), height (metres or feet and inches), body mass index (kg/m^2), blood pressure, blood glucose, history information e.g. any previous weight loss (WL) attempts; details of their general practitioner and any medicines taken, programme inclusion and exclusion criteria, supply of orlistat, dates of visits to the programme and outcome of pharmacists' consultation including minimum weight loss required at three months.

Boots head office provided information about straight-line distances from the pharmacy to the client's home that were transformed from the partial postcodes.

4.2.5 Data analysis

Data were entered into a prepared Microsoft Office Access 2007 database and transferred to SPSS version 19.0 for analysis. Data were analysed both descriptively and inferentially. The demographic data analysis included clients' baseline data at entry to the programme which consisted of frequency counts, percentages, mean and standard deviations (SD). Clients' age was determined by subtracting their year of birth from the year of entry to the programme.

A chi-square test (χ^2) was used to investigate differences in baseline data relating to gender, age and BMI for clients who participated in the programme for less than three months with those who participated for three months or more.

The Wilcoxon Signed Rank Test was used for continuous data in terms of comparing weight and BMI at baseline and at three months because of non-normal distribution – see testing normal distribution, page 199. The Mann-Whitney U test was used to compare the categorical variables within the two groups (such as gender, age, time period of being in the programme, and characteristics of dropout group with remaining group) and the continuous variables (such as weight and BMI). The Kruskal-Wallis test was used to compare differences across groups of blood pressure and previous weight loss attempt, classified by weight. A two-tailed p-value < 0.05 was considered statistically significant.[165]

In addition, sensitivity analysis was performed only on the weight changes using a last-observation-carried-forward (LOCF) analysis that included all clients' records, where missing data were imputed by carrying forward the last measured observation.

4.3 Results

A total of 658 records were collected from the 10 pharmacies. Five hundred and fifty seven records were included in the study, and 101 records excluded. Records were excluded where they were not within the study time frame of 1st January 2006 and 31st January 2009 (n = 66) or no orlistat was supplied at the initial visit (n = 35) – see Table 4.1.

Table 4.1 Total of the included and excluded records

Records	Total records	
	n	%
Collected	658	100.0
Included	557	84.6
Excluded	101	15.4
Not in time frame (before 1 January 2006 or after 31 January 2009)	66	10.0
No orlistat supply at the initial visit	35	5.4
No reasons given for non-supply	19	2.9
Met the inclusion criteria but decided not to attend Boots programme	11	1.7
Met the inclusion criteria but clients declined to receive advice about orlistat	5	0.8

4.3.1 Reasons why orlistat was not supplied

It was found that 11 clients met the programme inclusion criteria but did not participate in the Boots programme. Reasons recorded for this were: the client decided not to participate and decided to try a different programme or continued to

try to lose weight on their own.

Other reasons why orlistat was not supplied were related to clients' health problems such as allergy, arthritis and high blood pressure; factors that did not necessarily exclude clients from the programme but led to the clients choosing not to participate due to these health issues – see Table 4.2.

Table 4.2 Characteristics of clients excluded due to not receiving orlistat (n = 35)

Characteristics	Number of clients or Mean ± SD	% or range
Gender		
Female	30	85.7
Male	5	14.3
Age at entry to programme (years, n = 19)*		
18-29	3	15.8
30-39	2	10.6
40-49	4	21.0
50-59	8	42.0
60 and older	2	10.6
Height (metre, n = 27)*	1.6 ± 0.1	1.5-1.76
Baseline weight (kg, n = 27)*	88.1 ± 12.3	71.2-120.2
BMI (kg/m^2)		
Baseline* (n = 29)	33.4 ± 4.4	28-47.1
Inclusion criteria** (n = 34)		
BMI ≥ 30	25	73.5
BMI ≥ 28 with one co-morbid health risk	9	26.5
Reasons for not participating in the programme		
Unknown	19	54.3
Met the inclusion criteria but decided not to attend Boots programme	11	31.4
Met the inclusion criteria but no advice of orlistat to clients	5	14.3

*This grouping does not total 35 due to missing data. **This BMI is for inclusion criteria for participating in this programme.

4.3.2 Completeness of customer record forms

Completion rates for baseline data in the customer record forms (CRFs) varied from 94% to 100%, with only six variables not being 100% completed – see Table 4.3. Random blood glucose (RBG) was less well completed at baseline with 94% of clients having this measure recorded. The completeness of records for both pharmacists reporting the clients value as following the inclusion criteria (or stating it was normal) in a check box or reporting biometric values was 98% for blood pressure and 94% for blood glucose. – see Appendix 11. Variables of blood pressure and blood glucose were not compulsory whilst other variables recorded during the client's initial visit, such as history information, inclusion and exclusion criteria, orlistat supply and the outcome of pharmacists' consultations, were fully completed.

Table 4.3 Completeness of data set at baseline (n = 557)

Variables*	Data set with complete information	(%)
Gender	554	99.5
Age	557	100
Height (metres)	556	99.8
Weight (kg)	556	99.8
BMI	557	100
Date of visits	557	100
BP recorded		
Systolic BP (SBP)	545	97.8
Diastolic BP (DBP)	545	97.8
Random BG recorded	524	94
Minimum weight loss required at 3 months (kg)	553	99.3

*Other variables were 100% completed.

4.3.3 Completeness of data at follow-up visits

Data noted at each follow-up visit included date of visit, orlistat supply, either weight and/or BMI and any consultation notes. A total of 1,141 follow-up visits were recorded for the 557 clients. Over two-thirds of visits had a record of orlistat supply (n = 797, 70%) and four-fifths had either weight or BMI recorded (n = 942, 83%). Consultation notes were optional, and 740 (65%) of visits had a comment from the pharmacist. Variables recording orlistat supply and consultation notes were not expected to be 100%. It was expected that either weight or BMI would be recorded. Both pharmacists and clients knew results from the printout of weight from the electronic scales. Clients needed to weigh themselves on every single visit which involved a pharmacists' consultation. If, for whatever reason this did not happen, clients were asked to weigh themselves before having their next visit. Pharmacists could then record how much clients had lost or gained since their previous visit.

4.3.4 Data checking and cleaning

A 10% random sample of clients' data was checked for data entry errors. Fifty-five client records were checked and one error was discovered. This error was 19 kg being entered as the minimum weight loss target at three months (5%) kg/lbs. After rechecking, it was amended by converting from pound (lbs) to kg = 7 kg.

Data cleaning was shown in Table 4.4 below.

Table 4.4 Data cleaning

Variables	Label and values*	No others values found
Client number	The range of client number was from 1 to 557.	✓
Store number	All values of store numbers were checked from Boots document.	✓
Gender	All values were 1 for male and 2 for female.	There were three missing values which were 999.
Age (years)		
In programme	Year of clients' participation was subtracted by year of clients' birth.	✓
In group	All values of age group were on the range from 1 to 5 1 = 18-29 years 2 = 30-39 years 3 = 40-49 years 4 = 50-59 years 5 = 60 years and older	✓
Postcode	All actual values were partial postcodes.	There were first three or four digits of postcodes recorded.
Clients' details	All values of all client detail variables were 0 for no and 1 for yes whether: Aged between 18 and 82 years Registered with a GP (doctor) Willing for Boots to contact doctors and referred clients for future treatment if necessary Agreed to a BP test and to a finger-prick blood sample for in store measurement of BP Agreed to proceed with treatment if appropriate and accepted any advice on diet, exercise and lifestyle changes from the Boots pharmacist	✓
Information received	All values of any direction of information received about BPWLP were multi-selection list as 0 for no and 1 for yes following: TV/radio, Magazine/newspaper, Boots leaflet, Recommendation from a friend, Internet, Other	One client did not answer for any type of information received so that 999 were entered.
Doctor's details	All values of all doctor's detail variables were 0 for absent and 1 for present.	✓

Table 4.4 (continued)

Variables	Label and values	No others values found
Any medicines prescribed by doctors or purchased over the counter	All values of all medicines taken variables were 0 for absent and 1 for present. If any medicines were taken, how many they were on the range from 0 to 4 0 = No medicines 1 = 1 medicine 2 = 2 medicines 3 = 3 medicines 4 = 4 or more medicines	✓
Previous weight loss attempts	All values of all previous weight loss attempts were 0 for absent and 1 for present. If clients had history of any previous weight loss attempts, what they were on the range from 0 to 8. 0 = No attempts 1 = Only diets 2 = Only exercise 3 = Only slimming pills 4 = Both diets and exercise 5 = Either diets or exercise and slimming pills 6 = All attempts of diets, exercise and slimming pills 7 = Other attempts e.g. BPWLP, herbal medicines, other programmes 8 = Multi-attempts e.g. Any of diets, exercise, slimming pills or others	✓ Details of clients' previous weight loss attempts were completely explained in either results or discussions.
Inclusion criteria	All values of all four inclusion criteria were 0 for no and 1 for yes whether: Clients' BMI was ≥ 30 kg/m^2 Clients' BMI was ≥ 28 kg/m^2 with one-co-morbid health risk Clients met the inclusion criteria for the BPWLP Clients were eligible for the BPWLP All value of BMI ≥ 28 kg/m^2 with one-co-morbid health risk were multi-selection list as 0 for no and 1 for yes following:	✓

Table 4.4 (continued)

Variables	Label and values	No others values found
Inclusion criteria (continued)	Non insulin dependent diabetes, Raised cholesterol, Stress incontinence, Any heart disease, Hiatus Hernia, Awaiting surgery, High BP, Pituitary disease, Gallstones, Gastro-Oesophageal Reflux disease (GORD), Any respiratory disease (e.g. asthma, COPD, sleep apnoea), Osteoarthritis of a weight-bearing joint (e.g. knee, spine, hip), Other	✓
Exclusion criteria	All values of all eight exclusion criteria were 0 for no and 1 for yes whether: Clients were pregnant, breast-feeding, insulin-dependent diabetes, any present liver; gall bladder or bile duct problems, surgery for weight loss, gastrointestinal malabsorption problems, sensitivity to orlistat, taking any concomitant medication (amiodarone, acarbose, ciclosporin)	✓
Orlistat advice to clients	All values of all orlistat advice were 0 for no and 1 for yes whether: Clients agreed to use orlistat only whilst following the BPWLP with diet and exercise recommendation Clients were aware orlistat can produce side effects in the digestive system Clients agreed to read patient information leaflet (PIL) and followed the instructions before taking orlistat Clients were informed about orlistat will be discontinued if their weight loss was less than 5% of the initial weight after 12 weeks Clients were informed about orlistat is use for weight loss	✓
Outcome of consultation	All values of outcome of consultation were: 1 = Client is suitable for entry and has decided to buy treatment from Boots. 2 = Client is suitable but has decided to go to their doctor. 3 = Client is suitable but has decided not to buy treatment from Boots.	✓
Doctor referral	Boots pharmacist explained to their clients that if diabetes or high BP may not aware of their condition, there were no obvious signs or symptoms, the affected individual client may feel well and completely normal. If a pharmacist found client's BP or BP was outside the expected range or any other significant concerns, client will be advised to consult their doctor. If client's BP > 140/85 mmHg or BG ≥ 5.6 mmol/L, pharmacist will consider No, Yes or Refer	✓

Table 4.4 (continued)

Variables	Label and values	No others values found
Doctor referral (continued)	All values were: 0 for no, 1 for yes, 2 for refer, 3 for yes and refer	✓
Client's biometrics on entry to the programme	Height (metres/feet and inches) Weight (kg/lbs) BMI (kg/m^2) Minimum weight loss required at 3 months (5%) kg/lbs Final target weight (kg/lbs) Systolic/Diastolic BP (mmHg) Random BG (mmol/L)	At least two actual values of height, weight or BMI recorded were able to be calculated.
Client's consent Pharmacist's signature	All values were: 0 for signature absence, 1 for signature presence Actual date to know what year clients participated in the programme	✓
Orlistat supply	All values were: 1 = 1-month supply of 84 orlistat 120 mg capsules 2 = One of 3-month supply of orlistat 120 mg capsules	✓
Checklist	A checklist for the dispensed pack which included 1) your step to successful weight loss leaflet, 2) patients' guide, 3) orlistat 120 mg capsules and 4) final check by pharmacist. All values of checklist were 0 for no, 1 for yes	✓
Date of visit Weight (kg/mlbs) BMI Consultation notes	All actual values were weight (kg/lbs) and/or BMI. All values of date of visit were 0 for not attending and 1 for attending All values of consultation notes were: 0 = No comments 1 = Problem note 2 = Neutral note 3 = Positive note 4 = All problem, neutral and positive notes 5 = Problem and neutral notes (1+2) 6 = Problem and positive notes (1+3) 7 = Neutral and positive notes (2+3)	✓ Details of side-effects note were completed by counting episode of side-effects

Table 4.4 (continued)

Variables	Label and values	No others values found
Side-effects	All values of side-effects were: 1 = Constipation 2 = Diarrhoea 3 = Headache 4 = Stomach ache 5 = Slight suffering of side-effects 6 = Loose stools 7 = Gastrointestinal system, dry mouth and disturbed sleep	✓

*All variables were checked for missing data. If it was found, values were 999.

4.3.5 Characteristics of clients

4.3.5.1 Clients' demographics

Most clients were female (n = 514, 93%), were aged 40-59 years (n = 285, 51%) and were currently using medicines either prescribed by their doctor or purchased over the counter (n = 340, 61%). Mean weight was 92.8 kg and BMI at baseline was 34.5 kg/m^2, whilst baseline mean systolic and diastolic blood pressure and random blood glucose were 127 mmHg, 85 mmHg and 5.6 mmol/L, respectively – see Table 4.5.

Table 4.5 Client characteristics at baseline (n = 557)

Characteristics	Number of clients or Mean ± SD	% or range
Client's details		
Gender*		
Female	514	93.0
Male	40	7.0
Age at entry to programme, years		
18-29	54	9.7
30-39	125	22.4
40-49	139	25.0
50-59	146	26.2
60 and older	93	16.7
Currently taking any medicines prescribed or purchased		
Yes	343	61.6
No	214	38.4
Number of medicines prescribed or purchased		
No medicine	214	38.4
1 medicine	132	23.7
2 medicines	80	14.4
3 medicines	55	9.9
4 or more medicines	76	13.6
Client's biometrics		
Height, metres (n = 556)*	1.6 ± 0.7	1.45-1.91
Weight, kg (n = 556)*	92.8 ± 15.6	59.4-158.7
Baseline BMI (kg/m^2)	34.5 ± 4.9	28-55.1
BP, mmHg (n = 545)*		
Systolic BP	127.4 ± 18.1	92-198
Diastolic BP	85.3 ± 11.3	55-127
Random BG, mmol/L (n = 524)*	5.6 ± 1.7	2.6-18.5
Minimum weight loss required at 3 months, kg (n = 553)*	4.6 ± 0.8	3-7.9

*This grouping does not total 557 due to missing data.

Table 4.5 (continued)

Characteristics	Number of clients or Mean ± SD	% or range
Pharmacist's checklist for inclusion and exclusion criteria		
Inclusion criteria[**]		
BMI ≥ 30 kg/m^2	483	86.7
BMI ≥ 28 kg/m^2 with at least one co-morbid health risk	74	13.3
Orlistat supply[***]		
3-month option	477	85.6
1-month option	80	14.4

[**]This BMI is for inclusion criteria for participating in this programme.

[***]3-month option is a supply of 3x84 orlistat 120 mg capsules. 1-month option is a supply of 84 orlistat 120 mg capsules

4.3.5.2 Clients' details

The inclusion criteria for a record of clients' details were that they should be aged between 18 and 82 years, and that all were willing for Boots to contact their doctor or refer them for future treatment if necessary. They also all agreed to the measurement of their blood pressure and to provide a finger-prick blood sample for in-store measurement of blood glucose. All agreed to proceed with treatment if appropriate and accept any advice on diet, exercise and lifestyle changes that might be offered from the Boots pharmacist. Clients received information about BPWLP through a variety of methods, most having found out about the programme from a Boots leaflet in one of their pharmacies (60%) – see Table 4.6.

Table 4.6 Sources of information about BPWLP (n = 557)

Information source	Number of clients*	%**
Television/radio	23	4.1
Magazine/newspaper	50	9.0
Boots leaflet (in store)	337	60.6
Recommendation from a friend	88	15.8
Internet	49	8.8
Other	44	7.9

*Many clients received more than one type of BPWLP information.

**One client did not select an information source.

4.3.6 Other variables measured at the initial visit

4.3.6.1 BMI and health risks

Over one-fifth of clients (n = 74) had a BMI 28 kg/m^2 or more, with at least one co-morbid health risk; the remainder having a BMI of 30 kg/m^2 or more. Over two-thirds (n = 51) of those with a BMI between 28 and 30 kg/m^2 had only one co-morbid health risk. The most frequent co-morbid health risks were osteoarthritis of a weight-bearing joint (n = 18, 27%), followed by high BP (n = 14, 21%) and gastro-oesophageal reflux disease, GORD (n = 14, 21%) – see Table 4.7.

Table 4.7 Clients with BMI < 30 kg/m^2 and their co-morbid health risks (n = 74)

28 kg/m^2 ≤ BMI < 30 kg/m^2 with one co-morbid health risk	Number	%
Number of co-morbid health risks		
One co-morbid	51	68.9
Two co-morbid	16	21.6
Three co-morbid	5	6.8
Four co-morbid	2	2.7
Co-morbid health risk*		
Osteoarthritis of a weight-bearing joint (e.g. knee, spine or hip)	18	27.0
High BP (HBP)	14	21.0
Gastro-Oesophageal Reflux disease (GORD)	14	21.0
Raised cholesterol	12	18.0
Stress incontinence	11	16.4
Any respiratory disease (e.g. asthma, COPD, sleep apnoea)	8	12.0
Awaiting surgery	3	4.5
Non insulin dependent diabetes (NIDDM)	1	1.5
Hiatus Hernia	1	1.5
Others e.g. back or hip/knee joint problems, knee pain, breathlessness, osteoporosis, thyroid condition, glucose intolerance	20	30.0

*Many clients had more than one co-morbid health risk.

4.3.6.2 Previous weight loss attempts

Nearly two-thirds (n = 361) of clients' reported previous weight loss attempts involving both diet and exercise. About an eighth reported multiple previous attempts (n = 70) and diet only attempts (n = 62). Examples of multiple attempts involved diets, exercise, slimming pills (e.g. Reductil, Xenical, Adios), herbal medicines or other programmes – see Table 4.8.

Table 4.8 Clients' previous weight loss attempts before participating BPWLP (n = 557)

Previous weight loss attempts	Number	%
Both diet and exercise	361	64.8
Multiple attempts	70	12.6
Diet only	62	11.1
No weight loss attempts	33	6.0
Exercise only	19	3.4
Slimming pills in addition to diet or exercise	9	1.6
Slimming pills only	3	0.5

4.3.6.3 Medicines prescribed or purchased over the counter

Two-fifths of clients used medicines designed to deal with obesity-related health risks (n = 231) such as drugs used in heart failure, hypertension and hypercholesterolemia. One-fifth (n = 117) took medicines to treat other conditions, which included hormone replacement therapy (HRT), antibiotics, non-steroidal anti-inflammatory drugs (NSAIDs) or pain killers, antihistamine, anti-anxiety, anti-epileptic, anti-coagulant or anti-vertigo – see Table 4.9. The remaining two-fifths were not using any prescribed or over the counter medicines.

The medicines prescribed or purchased OTC were recorded by clients – see Appendix 12, Table A12.1. For those 74 clients who had a BMI of 28-29.9 kg/m^2 the pharmacist recorded co-morbid conditions as reported by the clients – see Table 4.7. A comparison for these 74 clients between their reported conditions and the medicines recorded showed a few discrepancies. Two clients reported taking metformin, but only one client reported diabetes – however the second client taking metformin reported having polycystic ovary disease. Details of the medicines recorded by clients with a BMI of 28-29.9 kg/m^2 are reported in Appendix 12, Table

A12.2.

Table 4.9 Clients' medicines prescribed or purchased over the counter (n = 557)

Medicines prescribed or purchased over the counter	Number*	%
Medicines for obesity-related health risks	231	41.5
Only medicines for health risk	144	25.9
Both medicines for health risk and other medicines	71	12.7
Vitamin supplement, medicines for health risk and other medicines	11	2.0
Vitamin supplement and medicines for health risk	5	0.9
No medicine	214	38.4
Other medicines	177	21.0
Only other medicines	86	10.2
Both medicines for health risk and other medicines	71	8.4
Vitamin supplement, medicines for health risk and other medicines	11	1.3
Vitamin supplement and others	9	1.1
Vitamins	42	7.6

*Many clients had more than one medicine, prescribed or OTC.

4.3.6.4 Straight-line distance and drive time

This straight-line distance[174, 175] was a proxy for drive time from the clients' home to the Boots pharmacy. The mean distance between Boots pharmacies and clients' homes was 6.5 km and driving time was 11.8 minutes. A drive time is important as straight-line distance may not accurately reflect the time taken for a person to travel from home to the pharmacy.[175] Time in travelling to the pharmacy is likely to better reflect whether or not a client is willing to make the effort to attend a particular pharmacy for a service – see Table 4.10.

Table 4.10 Straight-line distance and drive time to Boots pharmacies (n = 547)

Straight-line distance and drive time to Boots pharmacies	Mean ± SD (range)
Straight-line distance (km)	6.5 ± 6.4 (0.3-61.5)
Drive time (minutes)	11.8 ± 7.5 (0.89-64.62)

4.3.7 Consultation notes

The consultation notes in BPWLP consisted of three themes: positive, neutral (absence of problems) and problem notes – see Table 4.11. The positive notes included comments such as happy/pleased, achieved, brilliant/well or good/ok/fine. The neutral or absence of problems notes included no change in medication, no side or adverse effects, no problems and no contraindications. Problem notes included comments relating to the client's disappointment in weight loss, such as not having achieved a specific target, being unhappy or the reporting of side-effects such as constipation, diarrhoea, headache or stomach ache.

It was found that over one-third of clients (n = 231) had no comments in their consultation notes. About one-tenth (n = 49) of the consultation notes in BPWLP contained comments relating to clients' problems, whilst less than one-tenth included a neutral comment (n = 42), and 10% had positive comments (n = 52). Additionally, some notes had combinations of comments involving positive, neutral and problem notes relating to the weight loss programme (n = 67) – see Table 4.11.

Table 4.11 Consultation notes recorded for 557 clients

Consultation notes	Number	%
No comment	231	41.5
Problem notes only	114	20.5
Neutral or absence of problems only	86	15.4
Positive notes only	59	10.6
Positive and problem notes	25	4.5
Positive and neutral notes	18	3.2
Neutral and problem notes	15	2.7
All positive, neutral and problem notes	9	1.6

For 75 (14%) of the 557 clients, a side-effect related to orlistat was reported. Most of those reported side-effects were gastrointestinal disturbances with 40% reporting loose stools and over 25% diarrhoea – see Table 4.12.

Table 4.12 Side-effects recorded by pharmacists as possibly or probably related to orlistat treatment (n = 75)

Episode of side-effects	Number of clients	%
Gastrointestinal system		
Loose stools*	30	40.0
Diarrhoea**	17	22.6
Slight suffering of side-effects	14	18.7
Constipation	3	4.0
Stomach ache	2	2.7
Others		
Gastrointestinal system, dry mouth and disturbed sleep	4	5.3
Diarrhoea, stomach pain, nausea, vomit or dizziness	3	4.0
Headache	2	2.7

*Included fatty/oily stool, liquid/soft stools

**Uncontrolled oily discharge included faecal incontinence, flatus with discharge and oily spotting.

4.3.8 Participation in the BPWLP

4.3.8.1 Dropout

Using the dates recorded in clients' records, 84% (n = 468) returned for their follow-up visit at one month, and 38% (n = 214) returned for the 3-month follow-up visit. During the follow-up visits, most of these clients were supplied with a further treatment of orlistat: 95% (n = 444/468) at one month and 55% (n = 115/207) at three months – see Appendix 13.

Most clients continued in the programme for at least one follow-up with 85 (15.3%) not returning for any follow-up. One-third of the 468 clients who attended the programme at one month opted not to continue – see Table 4.13.

Table 4.13 Number and percent of clients who attended and did not attend in the programme follow-up visits (n = 557)

Particular time at follow-up visits	Month 1 (%)	Month 3 (%)
Attended	468 (84)	207 (37)
Continued	271 (48.6)	98 (17.6)
Left programme	197 (35.4)	109 (19.4)
Did not attend	89 (16)	68 (12)
Expected to continue programme later	4 (0.7)	68 (12)
Left programme	85 (15.3)	-

Reasons for leaving the programme were recorded for most clients, and these included achieving desired weight loss, personal circumstances and dissatisfaction with side-effects. Almost half of the clients who left the programme after three months had achieved the desired weight loss – see Table 4.14.

Table 4.14 Clients' reasons for leaving the programme at 1- and 3-month

Clients' reasons	Number of clients leaving the programme at 1 month (n = 197)		Number of clients leaving the programme at 3 months (n = 109)	
	n	%	n	%
Returned at particular time point and left				
No reason recorded	72	36.6	16	14.6
Achieved the desired weight loss	30	15.2	47	43.0
Personal reasons e.g. continued on own, holidays or moved	25	12.7	13	12.0
Dissatisfied with side effects	25	12.7	9	8.2
Health-related problems	21	10.7	4	3.7
Did not achieve the desired weight loss	10	5.0	15	13.8
Refund	8	4.1	-	-
Gained weight	5	2.5	3	2.7
Behaviour reasons e.g. lack of motivation	1	0.5	1	1.0
Others e.g. not happy, disappointed	-	-	1	1.0
Total	197	100.0	109	100.0

4.3.8.2 Comparison of characteristics between clients who remained in the programme for less than three months and those who remained for three months or more

There was a statistically significant difference between the ages of those continuing in the programme for at least three months and those who left earlier ($\chi^2 = 10.22$, $p = 0.001$). Younger clients were less likely to remain in the programme for three months than those aged 50 years and over – see Table 4.15. In contrast, there were no significant differences in the gender ($\chi^2 = 0.47$, $p = 0.49$) and BMI ($\chi^2 = 1.52$, $p = 0.68$) of clients, relative to length of time in the programme.

Table 4.15 Differences between characteristics of clients who stayed less than 3 months and at least 3 months

Characteristics	Dropout before 3 months (n = 391)		Stayed at 3 months and over (n = 166)		Total (%)	χ^2	*p*-value*
	n	%	n	%			
Gender (n = 554)							
Female	359	92.3	155	93.9	514 (92.8)	0.47	0.49
Male	30	7.7	10	6.1	40 (7.2)		
Age, years (n = 557)							
18-49	241	61.6	78	47.0	319 (57.3)	10.22	0.001
50 and older	150	38.4	88	53.0	238 (42.7)		
BMI (kg/m^2)							
28.0-29.9	50	12.8	24	14.5	74 (13.3)	1.52	0.68
30.0-34.9	201	51.4	77	46.4	278 (49.9)		
35.0-39.9	98	25.1	48	28.9	146 (26.2)		
≥ 40	42	10.7	17	10.2	59 (10.6)		

*p-value < 0.05 considered statistically significant.

4.3.9 Effects of orlistat 120 mg on body weight and BMI at three months

This section includes testing for a normal distribution, changes in weight and BMI at three months.

4.3.9.1 Testing for a normal distribution

Wilcoxon Signed Rank test (W) was used to test changes in weight and BMI before and after participating in the programme. The reason for this choice was that both parameters were non-parametrically distributed. This test was designed for use with the repeated measures on two different occasions.[165] Using the same method to test

for normality, as in Chapter 3 (page 155), three procedures were employed: graphical methods (histogram, a curve pattern in the corresponding Q-Q plot and detrended normal Q-Q plots), numeric methods (skewness and kurtosis indices) and a formal normality test (the Kolmogorov-Smirnov test).

Although both skewness and kurtosis are zero in a normal distribution, their values in this study were 0.97 and 1.41 in weight and 1.55 and 3.24 in BMI, respectively. The further away from zero, the more non-normal the distribution; the non-normal distribution was analysed using non-parametric statistics – see Appendix 14. Results of the Kolmogorov-Smirnov test showed significant value smaller than 0.05 which indicates a non-normal distribution. The *p*-values of weight and BMI data were both less than 0.05; therefore, both mean weight and mean BMI at baseline were not normally distributed – see Table 4.16.

Table 4.16 Tests of normality for both weight and BMI

Tests of normality	Weight (kg)	BMI (kg/m^2)
Skewness	0.97	1.55
Kurtosis	1.41	3.24
Kolmogorov-Smirnov*	0.000	0.000

*Significant value < 0.05

Testing normality for the variables of age, length of treatment, blood pressure and blood glucose at baseline were conducted as above. Graphical interpretation and the values of skewness and kurtosis were used to assess normality. There was only skewness and kurtosis of age shown by the parameters nearest to zero, which were 0.12 and -0.58, respectively. The remaining data for the four characteristics of age,

length of treatment, blood pressure and blood glucose were skewed – see Appendix 14. Results of the Kolmogorov-Smirnov statistic showed that significant values of length of treatment, systolic and diastolic blood pressure and random blood glucose were smaller than 0.05 which defines the results as constituting a non-normal distribution. Therefore, only age was normally distributed – see Table 4.17.

Table 4.17 Tests of normality for five characteristics data

Tests of normality	Age (years)	Length of treatment (years)	BP (mmHg)		Random BG (mmol/L)
			Systolic BP	Diastolic BP	
Skewness	0.12	0.73	0.73	0.45	2.81
Kurtosis	-0.58	0.55	0.55	0.38	14.71
Kolmogorov-Smirnov*	0.81	0.000	0.004	0.020	0.000

*Significant value < 0.05

4.3.9.2 Weight change

There was a statistically significant reduction in median weight at three months ($z = -11.4$, $p < 0.001$). The median value on weight change decreased from baseline ($Md = 90.7$) to three months ($Md = 85.3$) – see Table 4.18.

Table 4.18 Changes in clients' weight at baseline and 3 months for completers only

Weight (kg)	Time	
	Baseline (n = 556)*	Month 3 (n = 166)
Median	90.7	85.3
Percentiles		
25th	81.2	76.5
75th	100.9	94.8
Z-value**	-	-11.4
p-value***	-	< 0.001

*One client had no height and weight recorded.

**Z-value = The number of standard errors to test statistic Wilcoxon Signed Rank test (W) to approximate the distribution.

****p*-value < 0.05 considered statistically significant.

At three months, two-thirds of clients (n = 110/166, 66%) had lost between 3.00 kg and 7.99 kg. Meanwhile, five percent of clients gained weight at three months – see Table 4.19.

Table 4.19 Weight changes at three-months for completers only

Weight change (kg)	Clients' weight changes at 3 months (n = 166)	
	n	%
Gain	9	5.4
No change	1	0.6
Loss		
0.01-0.99	4	2.4
1.00-2.99	18	10.8
3.00-4.99	46	27.8
5.00-7.99	64	38.6
8.00-10.99	19	11.4
11.00-13.99	4	2.4
≥ 14.00	1	0.6

Sixty-two percent of completers (n = 103) met the three-month weight loss target of at least 5% of their initial body weight at three months – see Table 4.20.

Table 4.20 Percentage of weight change at three months for completers only compared with baseline

Percentage of weight change	Month 3 (n = 166)	
	n	%
Decrease from baseline weight		
0-4.9%	54	32.6
5-9.9%	92	55.4
≥ 10%	11	6.6
Increase from baseline weight		
0-4.9%	7	4.2
5-9.9%	1	0.6
≥ 10%	1	0.6

Weight change at three months was divided into three groups: 1) successful – lost at least 5% of the initial weight 2) maintainers or improvers – lost < 5% of the initial weight and 3) the unsuccessful group (or gainers) gained weight at three months. A weight loss of around 5-10% for a period of three months is enough to see an improvement in health.[15] Due to the small numbers in the unsuccessful group, the successful group was compared with the maintainers or improvers – see Table 4.21.

There was no difference in the proportion of women being successful on the programme, compared with maintainers or improvers – see Table 4.21; $z = -0.06$, $p = 0.95$. At three months, although completed clients who were successful (84.5 kg) had lower median weight than those who were maintainers or improvers (87.2 kg), the

median BMI in the successful group (32.1 kg/m^2) was higher than those in the maintainers or improvers group (31.6 kg/m^2).

Table 4.21 Baseline characteristics of completed clients classified according to their success with the percentage at 3 months

Baseline characteristics (n = 557)	Successful (Lost ≥ 5% of initial body weight, n = 103)	Maintainers or improvers (Lost 0-4.9% of initial body weight, n = 54)	Z-value[a]	*p*-value[b]
Gender: Male/Female[c] (%)			-0.41	0.05
40/514 (7.0/93.0)	9/93 (8.7/90.3)	6/48 (11.1/88.9)		
Age (range), years			-0.18	0.86
47 (18-82)	51 (18-74)	49 (27-74)		
BMI (range), kg/m^2			-1.00	0.32
34.5 (28-55.1)	32.1 (25.6-50.2)	31.6 (25.6-53.5)		
Weight (range), kg			-0.06	0.95
92.8 (59.4-158.7)	84.5 (61.7-145.1)	87.2 (56.7-131.5)		
Weight change (range), kg			-9.61	<0.001
-	6.4 (3.6-16.8)	3.1 (0.0-5.4)		

[a]Z-value = The number of standard errors to test statistic Mann-Whitney U test (U) to approximate the distribution.

[b]*p*-value < 0.05 considered statistically significant.

[c]This grouping does not total 157 due to missing data.

4.3.9.3 BMI change

There was a statistically significant reduction in BMI at three months (z = -12.2, $p < 0.001$). The median value of BMI level decreased from 33.4 kg/m^2 at baseline to 31.6 kg/m^2 at three months, *Md* = 1.8, 5.7% - see Table 4.22.

Table 4.22 Change in clients' BMI at baseline and 3 months for completers only

BMI (kg/m^2)	Time	
	Baseline (n = 557)	Month 3 (n = 166)
Median	33.4	31.6
Percentiles		
25th	31.1	29.1
75th	36.7	35.1
Z-value*	-	-12.2
p-value**	-	< 0.001

*Z-value = The number of standard errors to test statistic Wilcoxon Signed Rank test (W) to approximate the distribution.

***p*-value < 0.05 considered statistically significant.

Most clients had BMI level of 30.0-34.9 kg/m^2 at baseline (n = 278, 50%) and month three (n = 63, 38%) – see Table 4.23. The percentage of clients who had a BMI level of 30 kg/m^2 or greater was 87% at baseline and 63% at three months.

Table 4.23 Changes in clients' BMI at baseline and 3 months for completers only

BMI (kg/m^2)	Clients' BMI changes at 3 months			
	Baseline, n = 557	%	Month 3, n = 166	%
25.0-27.9	-	-	19	11.4
28.0-29.9	74	13.3	43	25.9
30.0-34.9	278	49.9	63	38.0
35.0-39.9	146	26.2	30	18.1
≥ 40	59	10.6	11	6.6

For clients who remained in the programme at three months, 34 (21%) clients decreased their BMI level from obesity class I to overweight (25.0-29.9 kg/m^2). Twenty-two (13%) clients decreased their BMI level from obesity class II to obesity class I whilst 16 (10%) of clients decreased a BMI level from overweight with one-

comorbidity (28.0-29.9 kg/m^2) to 25.0-27.9 kg/m^2. For 82 (49%) clients there was no change in BMI classification – see Table 4.24.

Table 4.24 Changes of BMI level at three months for completers only (n = 166)

BMI (kg/m^2)	Number of clients' BMI changes	
	Month 3	%
No change	82	49.4
Change from overweight with one-comorbidity to 25.0-27.9	16	9.6
Decreased from		
Obese class I to overweight	34	20.5
Obese class II to overweight	1	0.6
Obese class II to obese class I	22	13.3
Obese class III to obese class II	7	4.2
Increased from		
Obese class I to obese class II	3	1.8
Obese class II obese class III	1	0.6

4.3.10 Comparison of baseline biometric data by age, gender and length of time in the programme

A comparison of baseline biometric data was done to find if there were differences.

4.3.10.1 Length of time in the programme

The median baseline diastolic blood pressure of clients who participated in the programme for up to three months (*Md* = 84.0, n = 445) was lower than the baseline median of clients who participated in the programme for more than three months (*Md* = 87.5, n = 100), z = -2.11, $p < 0.03$ – see Table 4.25. No other baseline biometric

data showed statistically significant differences related to length of time in the programme.

Table 4.25 Differences of clients' weight, BMI, BP and BG by the time period of being in the programme

Baseline measures	Up to 3 months (n = 452)		More than 3 months (n = 105)		Z-value*	*p*-value**
	Median	N	Median	N		
Weight (kg) ***	90.7	451	89.8	105	-1.01	0.31
BMI (kg/m^2)	33.4	452	33.2	105	-0.64	0.52
SBP (mmHg) ***	124.0	445	127.0	100	-1.43	0.15
DBP (mmHg) ***	84.0	445	87.5	100	-2.11	0.03
BG (mmol/L) ***	5.3	429	5.3	95	-0.50	0.61

*Z-value = The number of standard errors to test statistic Mann-Whitney U test to approximate the distribution.

***p*-value < 0.05 considered statistically significant.

***This grouping does not total 557 due to missing data.

There were no significant differences in the proportion of clients who participated in the programme up to the three months' point from those who participated for more than three months by gender ($\chi^2 = 1.11$, $p = 0.29$) or age ($\chi^2 = 6.93$, $p = 0.14$) – see Table 4.26.

There were no significant differences in the proportion of clients who participated in the programme up to three months with those who participated for more than three months, in terms of medicines prescribed or purchased ($\chi^2 = 1.99$, $p = 0.16$), previous weight loss attempts ($\chi^2 = 0.94$, $p = 0.63$), blood pressure ($\chi^2 = 3.15$, $p = 0.21$), blood glucose ($\chi^2 = 0.12$, $p = 0.73$), health risk ($\chi^2 = 0.09$, $p = 0.76$), straight-line distance ($\chi^2 = 1.49$, $p = 0.22$) and drive time ($\chi^2 = 0.40$, $p = 0.53$), respectively.

Interestingly, clients with baseline blood pressure greater than or equal to 140/85 mmHg represented a higher proportion of clients remaining in the programme than those with baseline blood pressure lower than or equal to 140/85 mmHg ($\chi^2 = 3.15$, $p = 0.21$) – see Table 4.26.

Table 4.26 Differences among clients' characteristics by the time period of being in the programme

Characteristics	Up to 3 months		More than 3 months		Total (%)	χ^2	*p*-value*
	n	%	n	%			
Gender (n = 554)						1.11	0.29
Female	415	92.2	99	95.2	514 (92.8)		
Male	35	7.8	5	4.8	40 (7.2)		
Age, years (n = 557)						6.93	0.14
18-29	49	10.8	5	4.8	54 (9.7)		
30-39	104	23.0	21	20.0	125 (22.4)		
40-49	109	24.2	31	29.5	140 (25.1)		
50-59	120	26.5	25	23.8	145 (26.0)		
60 and older	70	15.5	23	21.9	93 (16.7)		
Medicines prescribed or purchased OTC (n = 557)						1.99	0.16
No medicines	180	39.8	34	32.4	214 (38.4)		
At least one medicine	272	60.2	71	67.6	343 (61.6)		

*p-value < 0.05 considered statistically significant.

Table 4.26 (continued)

Characteristics	Up to 3 months		More than 3 months		Total	χ^2	*p*-value*
	n	%	n	%			
Previous weight loss attempts						0.94	0.63
Both diet and exercise	292	64.6	69	65.7	361 (64.8)		
Other attempts	135	29.9	28	26.7	163 (29.3)		
No attempts	25	5.5	8	7.6	33 (5.9)		
BP level recorded, mmHg (n = 545)						3.15	0.21
≤ 129/84	196	44.0	37	37.0	233 (42.8)		
130/85 - 139/89	95	21.3	19	19.0	114 (20.9)		
≥ 140/85	154	34.7	44	44.0	198 (36.3)		
BG level recorded, mmol/L (n = 524)						0.12	0.73
< 5.6	249	58.0	57	60.0	306 (58.4)		
≥ 5.6	180	42.0	38	40.0	218 (41.6)		
Health risks						0.09	0.76
No cormorbid risks	391	86.5	92	87.6	483 (86.7)		
At least one cormorbid risk	61	13.5	13	12.4	74 (13.3)		
Straight-line distance to pharmacy, km (n = 153)						0.12	2.38
< 10	360	81.4	80	76.2	440 (79.0)		
≥ 10	82	18.6	25	23.8	107 (21.0)		
Drive time to pharmacy (minutes)						0.40	0.53
< 15	329	74.4	75	71.4	404 (72.5)		
≥ 15	113	25.6	30	28.6	143 (27.5)		

*p-value < 0.05 considered statistically significant.

4.3.11 Characteristics of clients associated with weight reduction at three months

The association between baseline characteristics and weight reduction are described in this section.

Women were more likely to be successful in losing at least 5% from baseline body weight at three months, compared with men ($\chi^2 = 4.34$, $p = 0.04$). No other baseline characteristics were found to be associated with being successful in losing weight (at least 5% at three months) – see Table 4.27.

Table 4.27 Baseline characteristic associated with weight reduction at three months (n = 157)

Characteristics	Successful (n = 103)		Maintainer/Improver (n = 54)		Total (%)	χ^2	*p*-value*
	n	%	n	%			
Gender (n = 156)						4.34	0.04
Female	99	97.1	48	88.9	147 (94.2)		
Male	3	2.9	6	11.1	9 (5.8)		
Age, years (n = 155)						1.06	0.30
18-49	45	44.1	28	52.8	73 (47.1)		
50 and older	57	55.9	25	47.2	82 (52.9)		
Medicines prescribed or purchased OTC						0.83	0.31
No medicines	36	35.0	15	27.8	51 (32.5)		
At least one medicine	67	65.0	39	72.2	106 (67.5)		
Previous weight loss attempts						1.56	0.46
Both diet and exercise	70	68.0	33	61.1	103 (65.6)		
Other attempts	25	24.3	18	33.3	43 (27.4)		
No attempts	8	7.7	3	5.6	11 (7.0)		
BP level recorded, mmHg (n = 151)						2.70	0.26
≤ 129/84	41	41.4	17	32.7	58 (38.4)		
130/85 - 139/89	16	16.2	14	26.9	30 (19.9)		
≥ 140/85	42	42.4	21	40.4	63 (41.7)		
BG level recorded, mmol/L (n = 146)						0.09	0.76
< 5.6	52	55.9	31	58.5	83 (56.8)		
≥ 5.6	41	44.1	22	41.5	63 (43.2)		

*p-value < 0.05 considered statistically significant.

Table 4.27 (continued)

Characteristics	Successful (n = 103)		Maintainer/Improver (n = 54)		Total (%)	χ^2	*p*-value*
	n	%	n	%			
Health risks						0.47	0.12
No comorbid risks	93	90.3	44	81.5	137 (87.3)		
At least one comorbid risk	10	9.7	10	18.5	20 (12.7)		
Straight-line distance to pharmacy, km (n = 153)						2.38	0.12
< 10	84	84.0	39	73.6	123 (80.4)		
≥ 10	16	16.0	14	26.4	30 (19.6)		
Drive time to pharmacy, minutes (n = 153)						1.38	0.24
< 15	75	75.0	35	66.0	110 (71.9)		
≥ 15	25	25.0	18	34.0	43 (28.1)		

*p-value < 0.05 considered statistically significant.

4.3.12 Characteristics of clients who achieved at least 5% weight loss

There were significantly different characteristics of clients who achieved at least 5% weight loss at three months. Women (*Md* = 6.4) were more likely to achieve weight loss compared with men (*Md* = 5.0, z = -2.08, p = 0.04). Clients with no comorbid risks (*Md* = 6.4) were more likely to achieve weight loss compared with those with at least one comorbid risk (*Md* = 5.5, z = -2.42, p = 0.01). The remaining characteristics were not found to be associated with clients who achieved at least 5% weight loss – see Table 4.28.

Table 4.28 Baseline characteristic associated with clients who achieved at least 5% of weight loss (n = 103)

Characteristics	Weight change (%)	Z-value*	*p*-value**
Gender (n = 102)		-2.08	0.04
Female (99)	6.4		
Male (3)	5.0		
Age, years (n = 103)		-0.25	0.81
18-49 (45)	6.4		
50 and older (58)	6.4		
Medicines prescribed or purchased OTC (n = 103)		-0.58	0.81
No medicines (36)	6.4		
At least one medicine (67)	6.4		
Previous weight loss attempts*** (n = 103)		4.18	0.81
Both diet and exercise (70)	6.4		
Other attempts (25)	6.3		
No attempts (8)	6.5		
BP level recorded, mmHg*** (n = 99)		1.59	0.45
≤ 129/84 (41)	5.9		
130/85 - 139/89 (16)	6.8		
≥ 140/85 (42)	6.4		
BG level recorded, mmol/L (n = 93)		-0.40	0.97
< 5.6 (52)	6.4		
≥ 5.6 (41)	6.4		
Health risks (n = 103)		-2.42	0.01
No comorbid risks (86)	6.4		
At least one comorbid risk (17)	5.5		

*Z-value = The number of standard errors to test statistic Mann-Whitney U test to approximate the distribution.

**p-value < 0.05 considered statistically significant.

***χ^2 = Value to evaluate differences in mean ranks across the groups of previous weight loss attempts and BP level using Kruskal-Wallis test.

Table 4.28 (continued)

Characteristics	Weight change (%)	Z-value*	*p*-value**
Straight-line distance to pharmacy, km (n = 101)		-1.44	0.15
< 10 (65)	6.4		
≥ 10 (35)	6.1		
Drive time to pharmacy, minutes (n = 101)		-0.33	0.74
< 15 (75)	6.4		
≥ 15 (26)	6.4		
Total	6.4		

*Z-value = The number of standard errors to test statistic Mann-Whitney U test to approximate the distribution.

**p-value < 0.05 considered statistically significant.

4.3.13 Sensitivity analysis

4.3.13.1 Weight change

A repeated measures Wilcoxson Signed Rank Test, using LOCF (Last-observation-carried-forward analysis), revealed a significant difference for median reduction in initial weight ($z = -16.4$, $p < 0.001$); at three months the median value of weight change ($Md = 88.0$) – see Table 4.29.

Table 4.29 Changes in clients' weight at baseline and 3 months for LOCF (n = 556[a])

Weight (kg)	Time	
	Baseline	Month 3
Median	90.7	88.0
Percentiles		
25th	81.2	79.7
75th	100.9	98.3
Z-value[b]	-	-16.4
p-value[c]	-	< 0.001

[a]One client had no height and weight recorded.

[b]Z-value = The number of standard errors to test statistic Wilcoxon Signed Rank test (W) to approximate the distribution.

[c]*p*-value < 0.05 considered statistically significant.

Identical analysis was conducted using the LOCF. More than two-fifths of clients being investigated (n = 232, 42%) had lost between 1.00 kg and 4.99 kg in weight, whereas 19% of clients had lost more than 5 kg – see Table 4.30.

Table 4.30 Weight changes at three-months for LOCF

Weight change (kg)	Clients' weight changes at 3 months (n = 556)	
	n	%
Gain	39	7.0
No change	143	25.7
Loss		
0.01-0.99	38	6.8
1.00-2.99	122	21.9
3.00-4.99	110	19.8
5.00-7.99	75	13.5
8.00-10.99	23	4.2
11.00-13.99	5	0.9
≥ 14.00	1	0.2

Using the LOCF analysis, only one-third (n = 131, 33.6%) met the three-month weight loss target of at least 5% of their initial body weight – see Table 4.31.

Table 4.31 Percentage of weight change at three months for LOCF comparing with baseline

Percentage of weight change	Month 3 (n = 556)	
	n	%
No change	143	25.7
Decrease from baseline weight		
0-4.9%	243	43.7
5-9.9%	120	21.6
≥ 10%	11	2.0
Increase from baseline weight		
0-4.9%	33	5.9
5-9.9%	4	0.7
≥ 10%	2	0.4

There was no difference in the proportion of women being successful on the programme compared with maintainers or improvers – see Table 4.32; z = -0.26, p = 0.05. At three months, LOCF clients who were successful (85.3 kg, 31.8 kg/m^2) had lower median weight and BMI than those who were maintainers or improvers (88.0 kg, 32.1 kg/m^2).

Table 4.32 Baseline characteristics of LOCF clients classified according to their success with the percentage at 3 months

Baseline characteristics (n = 557)	Successful (Lost ≥ 5% of initial body weight, n = 131)	Maintainers or improvers (Lost 0-4.9% of initial body weight, n = 243)	Z-value[a]	*p*-value[b]
Gender: Male/Female[c] (%)			-0.26	0.05
40/514 (7.0/93.0)	7/123 (5.4/94.6)	6/48 (9.5/90.5)		
Age (range), years			-2.4	0.16
47 (18-82)	50 (18-74)	45 (21-82)		
BMI (range), kg/m^2			-1.40	1.61
34.5 (28-55.1)	31.8 (25.6-50.2)	32.1 (25.6-54.0)		
Weight (range), kg			-1.12	0.26
92.8 (59.4-158.7)	85.3 (61.7-145.1)	88.0 (56.7-152.4)		
Weight change (range), kg			-15.27	<0.001
-	6.4 (3.6-16.8)	2.3 (0.01-6.40)		

[a]Z-value = The number of standard errors to test statistic Mann-Whitney U test (U) to approximate the distribution.

[b]*p*-value < 0.05 considered statistically significant.

[c]This grouping does not total 157 due to missing data.

4.3.13.2 BMI change

A repeated measures Wilcoxson Signed Rank Test, using LOCF, revealed a significant difference for median reduction in BMI (z = -12.8, $p < 0.001$); the median value of weight change at three months was 31.6 kg/m^2 – see Table 4.33.

Table 4.33 Change in clients' BMI at baseline and 3 months for LOCF (n = 557)

BMI (kg/m^2)	Time	
	Baseline (n = 557)	Month 3 (n = 166)
Median	33.4	31.6
Percentiles		
25^{th}	31.1	29.1
75^{th}	36.7	34.9
Z-value*	-	-12.8
p-value**	-	< 0.001

*Z-value = The number of standard errors to test statistic Wilcoxon Signed Rank test (W) to approximate the distribution.

***p*-value < 0.05 considered statistically significant.

All clients had BMI levels of 30.0-34.9 kg/m^2 at baseline (n = 278, 50%) and month three (n = 250, 44.9%) – see Table 4.34. The percentage of clients who had a BMI level of 30 kg/m^2 or greater was 87% at baseline and 96.6% at three months.

Table 4.34 Changes in clients' BMI at baseline and 3 months for LOCF (n = 557)

BMI (kg/m^2)	Clients' BMI changes at 3 months			
	Baseline	%	Month 3	%
25.0-27.9	-	-	19	3.4
28.0-29.9	74	13.3	107	19.2
30.0-34.9	278	49.9	250	44.9
35.0-39.9	146	26.2	130	23.3
≥ 40	59	10.6	51	9.2

Using LOCF analysis at three months, 57 (10.2%) clients decreased their BMI level from obese class I to overweight (25.0-29.9 kg/m^2). Thirty-six (6.5%) clients decreased their BMI level from obese class II to obese class I, whilst 28 (5%) clients decreased their BMI level from overweight with one-comorbidity (28.0-29.9 kg/m^2)

to 25.0-27.9 kg/m^2. With 416 (74.7%) clients there was no change in BMI classification – see Table 4.35.

Table 4.35 Changes of BMI level at three months for LOCF (n = 557)

BMI (kg/m^2)	Number of clients' BMI changes	
	Month 3	%
No change	416	74.7
Change from overweight with one-comorbidity to 25.0-27.9	28	5.0
Decreased from		
Obese class I to overweight	57	10.2
Obese class II to overweight	1	0.2
Obese class II to obese class I	36	6.5
Obese class III to obese class II	12	2.2
Increased from		
Obese class I to obese class II	3	0.4
Obese class II obese class III	2	0.3

4.3.13.3 Characteristics of clients associated with weight reduction at three months

There were no significant differences in the proportion of LOCF clients who were successful and maintainer or improver by gender (χ^2 = 1.94, p = 0.16) or age (χ^2 = 2.52, p = 0.052) – see Table 4.36.

In addition, there were no significant differences in the proportion of LOCF clients who were successful and were maintainers or improvers in terms of medicines prescribed or purchased (χ^2 = 0.12, p = 0.73), previous weight loss attempts (χ^2 = 1.00, p = 0.61), blood pressure (χ^2 = 5.07, p = 0.08), blood glucose (χ^2 = 0.03, p =

0.87), health risk ($\chi^2 = 2.07$, $p = 0.15$), straight-line distance ($\chi^2 = 0.01$, $p = 0.93$) and drive time ($\chi^2 = 0.75$, $p = 0.39$), respectively – see Table 4.36.

Table 4.36 Baseline characteristics of LOCF clients associated with weight reduction at three months (n = 374)

Characteristics	Successful (n = 131)		Maintainer/Improver (n = 243)		Total (%)	*p*-value*	χ^2
	n	%	n	%			
Gender (n = 372)						0.16	1.94
Female	123	94.6	219	90.5	342 (91.9)		
Male	7	5.4	23	9.5	30 (8.1)		
Age, years						0. 052	2.52
18-49	61	44.6	146	60.1	207 (55.3)		
50 and older	70	53.4	97	39.9	167 (44.7)		
Medicines prescribed or purchased OTC						0.73	0.12
No medicines	44	33.6	86	35.4	130 (34.8)		
At least one medicine	87	66.4	157	64.6	244 (65.2)		
Previous weight loss attempts						0.61	1.00
Both diet and exercise	90	68.7	161	66.3	251 (67.1)		
Other attempts	33	25.2	71	29.2	104 (27.8)		
No attempts	8	6.1	11	4.5	19 (5.1)		

*p-value < 0.05 considered statistically significant.

Table 4.36 (continued)

Characteristics	Successful (n = 131)		Maintainer/Improver (n = 243)		Total (%)	*p*-value*	χ^2
	n	%	n	%			
BP level recorded, mmHg (n = 365)						0.08	5.07
≤ 129/84	50	39.7	101	42.3	151 (41.4)		
130/85 - 139/89	19	15.1	55	23	74 (20.3)		
≥ 140/85	57	45.2	83	34.7	140 (38.4)		
BG level recorded, mmol/L (n = 358)						0.87	0.03
< 5.6	69	57.5	139	58.4	208 (58.1)		
≥ 5.6	51	42.5	99	41.6	150 (41.9)		
Health risks						0.15	2.07
No comorbid risks	118	90.1	206	84.8	324 (86.6)		
At least one comorbid risk	13	9.9	37	15.2	50 (13.4)		
Straight-line distance to pharmacy, km (n = 269)						0.93	0.01
< 10	100	77.5	187	77.9	287 (77.8)		
≥ 10	29	22.5	53	22.1	82 (22.2)		
Drive time to pharmacy, minutes (n = 269)						0.39	0.75
< 15	88	68.2	174	72.5	262 (71.0)		
≥ 15	41	31.8	66	61.7	107 (29.0)		

*p-value < 0.05 considered statistically significant.

4.4 Discussion

4.4.1 Main findings

4.4.1.1 Characteristics of clients

The objective of this study was to retrospectively evaluate weight loss resulting from the use of orlistat, in combination with diet and exercise, on obese clients who participated in a pharmacist-led weight management clinic for three months. This study evaluated the effectiveness of pharmacist-led weight management clinics, located in Boots stores in the East Midlands. Pharmacies were randomly selected using cluster sampling. A total of 557 customer records from 10 stores met the study's inclusion criteria.

The majority of clients in the programme were female, aged from 40 to 59 years. Mean weight and BMI at baseline were 92.8 kg and 34.5 kg/m^2, respectively. Mean blood pressure and random blood glucose (RBG) levels were within normal ranges.

Most clients found out about the BPWLP from an in-store leaflet – other sources of information about the programme were recommendations from friends, information in magazines or newspapers, the Internet and television or radio. Many of the clients had made previous weight loss attempts, primarily through both diet and exercise.

4.4.1.2 Changes in weight and BMI at three months

For those remaining in the programme, there were statistically significant differences in weight and BMI at three months, compared with their baseline data. Two-thirds

(62%) of clients who attended the programme at three months achieved at least a 5% reduction in body weight from their baseline measurement. However, around half of clients did not change their BMI category.

The sensitivity analysis showed one-third (33.6%) of clients who attended the programme at three months achieved at least a 5% reduction in body weight from their baselines, whereas around three quarters did not change their BMI category.

4.4.1.3 Predictors of remaining in the programme to three months and of achieving at least 5% weight loss

Women were more likely to have remained in the programme for at least three months than men ($\chi^2 = 1.11$, $p = 0.29$). It was notable that those who remained in the programme for at least three months had higher diastolic blood pressure compared with those who left the programme earlier ($z = -2.11$, $p < 0.03$).

The proportion of women who fell into the successful groups was not different from those in the maintainers or improvers groups. For a sensitivity analysis, this confirmed that there was statistically significant difference of weight loss between baseline and month 3.

4.4.2 Strengths and limitations

4.4.2.1 Strengths

The present study has provided valuable up-to-date evidence of a community pharmacy-based weight management intervention.

This study has examined the feasibility and efficacy of a weight loss programme in a community pharmacy setting. The supply of orlistat via a PGD, in combination with diet and exercise, was offered in the pharmacist-led weight management clinics located in Boots pharmacies.

The BPWLP was provided with and implemented by community pharmacists who were properly trained and were therefore able to offer competent professional advice to the programme's clients.

4.4.2.2 Limitations

There were several limitations to this study. Although it was based on a 'before and after' design, which involved a high proportion of dropouts, analysis showed the BPWLP was effective in assisting clients to lose weight.

There was a high dropout rate from this programme. The reasons why clients either did, or did not manage to achieve their weight loss targets were not recorded. However, there are many possible reasons behind success or failure, including level of motivation to achieve the desired weight loss, both positive and negative personal

circumstances and dissatisfaction with side-effects. Therefore, methods to improve client retention on weight loss programmes require further study.

Another limitation is that clients who were included in the programme were content to pay for the service and were determined as suitable for the BPWLP. The findings therefore cannot be generalised to non-commercial weight loss programmes.

Another limitation is that this study has relied for its data exclusively on clients' records of their personal details and pharmacists records, which were taken as part of the recruitment to the programme and were not intended to be used for research purposes. The impact of any poorly recorded data is unknown; however, there was a low rate of missing data, with most records being well completed by the pharmacists.

Other limitations relate to the potential bias from data based on the provision of services by a single commercial weight loss programme provider (Boots) and using data from only one geographical area – the East Midlands. The current-retrospective study had no comparison group either with another commercial weight loss programme or with a minimal intervention or control group. Without such a comparator, this study was subject to confounding: that is any weight loss results cannot be validly attributed to the programme.

As this study was a retrospective record review ideally data relating to all clients who had use the service between 2006 and 2011 (total population n = 20,195) at Boots pharmacies would have been included in the study. However the records where in the

form of paper records held at each store and only the number of clients using the service each month were reported centrally within Boots. Due to time and financial considerations it was not feasible to collect data for all clients who used the BPWLP. Therefore, a sample size calculation was needed to find an appropriate number of clients to include in the sample for research.

If we had used the total population of clients (20,195) for the study and assuming the results would be the same, just over 6,000 clients (30%) would remain in the programme for at least three months and more than 3,600 clients (18%) would achieve a weight loss of at least 5% of the initial weight.

Regarding objectives, long-term results (more than three months) and weight maintenance were not examined in this study. As regards clients remaining in the programme, there was a relatively low number of clients who did so, including some clients who remained in the programme at six months. The results of this study may not represent the obese male groups, due to low rates of participation by males in the weight management programme. Reasons for these low rates of participation are unknown.

Lastly, the programme specification did not require follow-up measurements of blood pressure and blood glucose. Therefore, it is not possible to determine the impact of any weight loss on these biometric measures.

4.4.3 Comparison with the previous studies

4.4.3.1 Characteristics of clients

At the baseline visit, the majority of clients in the programme were female and aged 40 to 59 years. This is similar to other studies where more women than men participated in weight management programmes.[176, 177] Average ages reported in such studies range from 42 to 56 years. Findings in the current study are similar to other commercial weight loss programmes; Shuger et al.[155] found participants' mean weight and BMI at baseline were 92.8 kg and 34.5 kg/m^2; these figures are lower than data cited in other previous studies.[176, 178]

The majority of adverse effects from other studies where orlistat was supplied were oily discharge,[179] diarrhoea,[75] faecal incontinence and flatulence,[178] respectively.[169, 180] In the study of Kaya et al.[75] gastrointestinal adverse effects (48%) were observed during a short follow-up period of 12 weeks. Fourteen percent of clients in the present study reported an episode of side-effects, mainly gastrointestinal events. Most adverse events were loose stools, diarrhoea, constipation, stomach ache or headache. This proportion of clients reporting adverse events is lower than that reported in other studies.[176, 178]

The treatment guidelines for obesity recommend maintaining a healthy weight by balancing 'calories in' and 'calories out' and eating a healthy diet. If people are managing to lose weight with lifestyle modification by improving their diets and exercise behaviours, they should not be considered for pharmacological treatment.[180] Both healthy eating and regular exercise are recommended for the treatment of

overweight and obese adults with a BMI < 40 kg/m^2.[69] In this current study and other studies,[181] most participants had made previous attempts to lose weight mostly through a combination of diet and exercise.

Clients in this current study had a higher drop-out rate than the rates in previous published studies of CWLPs. In Finley et al.,[182] 32% of clients were no longer active in the programme at six weeks and 53% had dropped out by 12 weeks, compared with an approximately 70% dropout in the present study at three months. In the current study, half of the clients dropped out at one month which was higher than another study where 37% of participants had left by four weeks.[183] One reason for leaving the programme was achieving the desired weight loss (n = 77, 25%). However, due to the programme specification those who did not achieve a 5% weight loss (n = 25, 8%) at three months were not able to continue. Published data on retention in a CWLP has found that reasons for leaving the programme included cost, scheduling conflicts/travel, tiring of the food, unrelated health issues, meeting weight loss goals and/or having stopped losing weight.[182]

Clients who remained at three months and over more likely to be older compared with those who left the programme before three months (χ^2 = 1.06, p = 0.30). Similarly, a systematic review by Moroshko et al.[184] demonstrated that younger patients had a higher attrition rate than older patients.

4.4.3.2 Changes in weight and BMI at three months

This study evaluated effectiveness of the pharmacist-led weight management clinic on weight loss at Boots UK. According to the NICE recommendations, patients who failed to achieve the 12-week weight loss criteria should be discontinued from orlistat.[15] Previous studies have shown that in patients with a weight loss of at least 5% during the first 12 weeks of orlistat treatment, around half had lost significantly more weight after two years.[170] In the present analysis, the initial target of weight loss at three months was a reduction in body weight of at least 5% of the baseline figure. Approximately two-thirds of clients remaining in the programme (n = 103, 62%) achieved meaningful weight loss at three months. Meaningful weight loss was defined as weight loss that met the target of at least 5% of the initial weight. Nevertheless, at three months, Kaya et al.[75] found that mean weight loss was 10% of the initial body weight, whilst the present study found percent weight loss was 6.4% of the clients' initial body weight. It would seem that clients in both studies were using different combinations of orlistat supply, diet, exercise and advice.

Heshka et al.[150] reported BMI decreased more in a structured commercial weight loss programme than in a self-help group at one year. However, there is evidence[75] about short-term (12 weeks) weight changes in obese patients, where decreases in BMI (mean -3.64 ± 0.97 kg/m^2) were recorded in a randomised trial. In comparison, clients' median BMI in the present study was reduced by 1.8 kg/m^2 at three months ($p < 0.001$).

4.4.3.3 Factors associated with length of time in the programme

Gender

Women were more likely to participate in the BPWLP and also to be successful in losing body weight baseline at three months compared with men ($\chi^2 = 4.34$, $p = 0.04$) who achieved at least 5% weight loss at three months. Likewise, the previous studies showed overall, both men and women achieved significant weight loss.[168, 170]

Achieving at least 5% weight loss

Clients with no comorbid risks were more likely to achieve at least 5% weight loss ($z = -2.42$, $p = 0.01$). Likewise, Finer et al.[176] claimed that obese patients using orlistat, who achieve and maintain 5-10% weight loss, have decrease in blood pressure and blood glucose levels. Although blood pressure and blood glucose in this study were measured by pharmacists during the client's initial visit to the weight loss clinic, pharmacists should also consider measuring blood pressure and blood glucose prior to clients leaving the programme, in order to compare pre- and post-levels for blood pressure and blood glucose. This would be useful to measure blood pressure and blood glucose. This information may be extra motivation for further weight loss if clients notice the beneficial effects on blood pressure and blood glucose.

4.5 Implications

This study would suggest that CWLP can be a successful programme for overweight or obese people who wish to lose weight. This programme can be provided in a pharmacy because this setting is easily accessed by clients. Not only can pharmacists take a more active high-profile role in weight loss management but they can also

inform clients about the health benefits of CWLPs.

A pharmacy-led weight management clinic with PGD supply should provide information on orlistat use, diet and exercise and weekly support to clients by following NICE guidance.[15] This may need to be tested in a NHS environment to determine whether or not this approach would positively target weight loss and could help to reduce the high dropout rate from such weight loss programmes.

Orlistat is currently available as a pharmacy medicine and is therefore easier to access than prescription only alternatives. To motivate people to pay for such a programme, providing full and detailed information by pharmacists is essential. Counselling and general advice from pharmacists can maximise clients' participating in the programme and understanding of how to successfully lose weight.

4.6 Recommendations for further study

The first recommendation is a RCT and economic evaluation of CWLPs. Secondly, research into reducing clients' dropout rates is recommended. Lastly, a comparison study is recommended for a prospective evaluation of clients who are supplied orlistat as a pharmacy medicine compared to those who are supplied orlistat as a part of the BPWLP. This would help to provide more data of CWLPs for further study.

4.7 Summary

The BPWLP involves the supply of orlistat 120 mg used in combination with diet and exercise. The evaluation showed that a community pharmacist-led weight management clinic was able to achieve weight loss at three months. Additionally, 62% of clients who remained in the programme lost a clinically meaningful amount of weight at three months; at least 5% of their baseline body weight.

Chapter 5

A survey evaluating clients' view of Boots Pharmacy Weight Loss Programme

This chapter describes the process of developing and validating a questionnaire used to investigate clients' view of the Boots Pharmacy Weight Loss Programme (BPWLP). The questionnaire was developed to determine clients' experiences of the BPWLP. It was designed to complement the evaluation of the BPWLP as described in Chapter 3 and Chapter 4. However, the questionnaire was not administered due to the low number of on-going clients in the programme.

5.1 Aim and objectives

The aim of this study was to develop a questionnaire for clients who participated in a pharmacist-led weight management clinic.

The objectives of the study were to:

- Develop the questionnaire
- Test the validity of the questionnaire

5.2 Methods

The questionnaire was developed with reference to the literature and discussions with supervisors and Boots staff, both from Head Office and the pharmacists providing the service – see Figure 5.1. It had been intended to administer the questionnaire to clients attending the BPWLP; however the launch of an over-the-counter version of orlistat (20 April 2009)[185] meant that the numbers of clients attending the patient group direction (PGD) service declined to the extent that distributing the questionnaire was not viable.

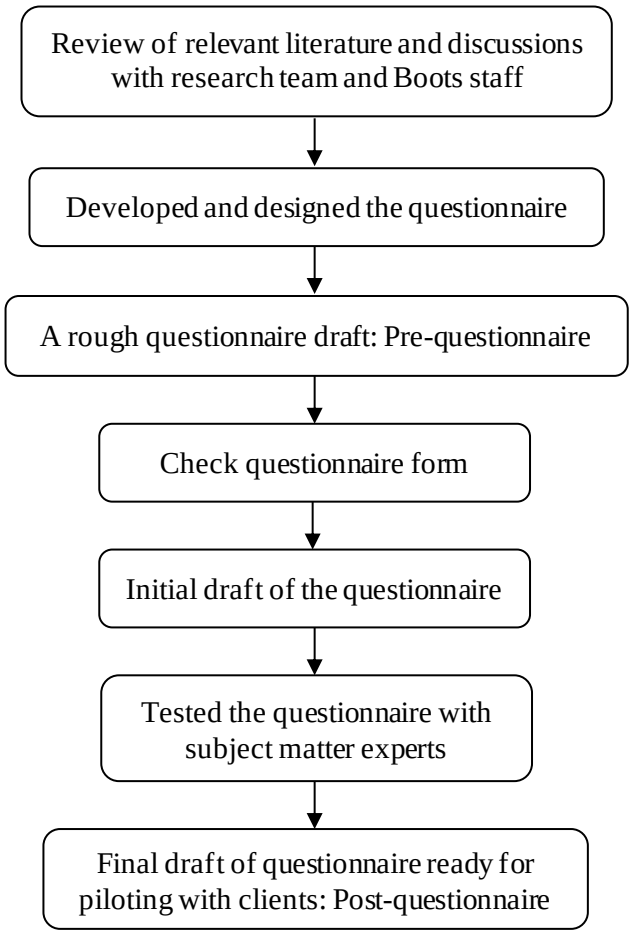

Figure 5.1 Process of developing and testing questionnaire

5.2.1 Literature review

The literature was searched for studies about evaluating health services which focused on weight management services, client views of weight management services,[186] measuring clients' views and factors associated with their experiences. Such information guided the development of the questionnaire.

5.2.2 Questionnaire design

5.2.2.1 Questionnaire content

The pilot customer questionnaire (CQ) for the BPWLP consisted of five sections briefly described below. The full questionnaire is in Appendix 15.

Section 1: Experiences of the Boots Pharmacy Weight Loss Programme

Eight questions related to clients' personal views about the programme and amount of time spent in the programme, their weight at entry to the programme and target weight loss at three months.

Section 2: Experiences of medicine

There were 11 questions about the medicine (orlistat 120 mg). The questions evaluated the clients' understanding of the medicine including how to take it, side effects experienced and other concerns.

Section 3: Experiences of weight loss service

Eighteen closed-questions included three questions about the facilities related to the service, and fifteen questions were about services received.

Section 4: Experiences of other weight loss programmes and activities[187]

In this section, clients are asked four closed-questions and give examples of the easiest and most successful methods clients' have used in previous weight loss attempts, diets and physical activities that respondents have tried.

Section 5: Demographics

This section involves nine questions asking about the following demographic characteristics.

- Gender: male/female[188, 189]
- Age group: 18-29, 30-39, 40-49, 50-59, 60-69, 70 years and older[190]
- Ethnic origin[34, 191]
- Legal marital status[32-34, 192, 193]
- Education[32, 33]
- Current work status[189]
- Family annual income[32, 33]
- Height and current weight
- Health status[190, 194, 195]

Questions were mainly closed-questions with categorical answers employing a 5-point Likert scale (range 5-strongly agree to 1-strongly disagree) as well as an option of not applicable (NA).

5.2.2.2 Testing the questionnaire

The questionnaire[171, 196] was tested for face validity and the sequence of questions:

- Face validity is the subjective assessment of the relevance of the questionnaire, including determining whether the questionnaire appeared to be relevant, reasonable, unambiguous, clear, well sequenced and well laid out. The questionnaire also assessed whether the content of the questionnaire comprehensively measures the scope of the characteristics of the weight loss service, such as the role of the pharmacist, using the medicine and clients' experiences.[171]
- The sequence of questions was also assessed to check there was a logical path through the questions to make the questionnaire easier for clients to complete and to easily feel the same format questions appeared together.[197]

The reason for testing the questionnaire[196] was to improve the quality of data collected and minimise non-sampling errors. Items were developed following a review of the literature and pilot study findings (Chapter 3) in order to ensure face validity. The face validity and sequence of questions was further discussed with two supervisors (a pharmacist and a general practitioner) and Boots staff, namely pharmacists who were providing the service in-store and head office staff.

Testing for face validity, also known as expert review, is not only a formal and systematic scrutiny of a questionnaire and very economical but it also identifies potential problems of question areas, layout and question wording.[198] Expert reviewers were asked to comment on the questionnaire design in terms of relevance, reason, clarity, layout, sequence of questions and content comprehensiveness by using a Validity Evaluation form – see Appendix 16.

Seventeen pharmacists were asked to comment on the questionnaires (five who worked for Boots and 12 who did not). Comments on the questionnaire were reviewed and the questionnaire was then revised.

5.3 Results

A total of 11 out of 17 experts commented on the questionnaire; three pharmacists who worked for Boots and eight who did not. Of those eight who were not employed by Boots, four worked in academia and four were community pharmacists. All pharmacists reviewed all questions to judge whether content was comprehensible and visual layout was good. They also completed a short questionnaire about their overall views of the questionnaire. About 10 of expert reviewers reported that the content was reasonable, and each of nine reviewers agreed that the questionnaire was relevant, had a good sequence of questions and was comprehensive – see Table 5.1.

Table 5.1 Experts view of the questionnaire (n = 11)

Comprehension from Weight Loss Programme Questionnaire	Yes	No	Not sure
Questions appear to be:			
1. Relevant	9	1	1
2. Reasonable	10	1	-
3. Unambiguous	5	-	6
4. Clear	5	1	5
5. Good layout	8	-	3
6. Sequence of questions	9	-	2
7. Content comprehensive	9	1	1
Total	55	4	18

Details of comments received from the pharmacists were summarised in Table 5.2. Responses to Section 1 and Section 3 suggested the questions were mostly considered relevant and clear; however, some questions needed to be reworded. Similarly, Section 4 was reworded to contain non-technical words to ensure respondents would understand. In contrast, Section 2 was restructured and redundant or repeated questions were removed. Overall the feedback comments suggested the sections were mostly relevant, had a logical good sequence and good layout.

Table 5.2 Pharmacists' comments on the questionnaire

Section	Pharmacists' comments (n = 11)
Section 1: Experiences of the Boots Pharmacy Weight Loss Programme (BPWLP) and Section 3: Experiences of other weight loss programmes and activities	Rewrite or reword some questions to make them clearer Overall, both sections were relevant and clear.
Section 2: Experiences of the medicine (orlistat) and services received	This section is quite long, unstructured and contained repeated questions. It is needed to be split into another section.
Section 4: About you	Replace some technical words with normal words that general or lay people can easily understand.
Others	Give an example how to fill out weight and height so respondents recognised the format. Examples of comments received: pretty good, quite comprehensive, fine, very clear with appropriateness, easy-to-answer questions, reasonable, unambiguous, in a sequence of questions and a good layout.

Following the pharmacists' assessment of the questionnaire a number of changes were made. Five questions were deleted, Section 2 was re-organised and the questions relating to facilities were moved to a separate section. A number of other changes were also made to improve the clarity of the questionnaire – see Table 5.3. The initial questionnaire and finalised questionnaire are shown in Appendix 15.

Table 5.3 Differences in the questionnaires before and after expert review

The previous questionnaire	The reviewed questionnaire
Section 1: There were 10 questions.	Section 1: There were 8 questions, Q*7 and Q10 were deleted.
Section 2: There were two parts in section 2: part 1 with 12 statements and part 2 with 19 statements.	Section 2: - Comments were quite long, unstructured and repeated questions so that it has been separated up into another section - One statement was deleted, and the sequence of statements was arranged and now there are 11 statements. - Deleted Q3 and added a space for clients to comment about the advantages of this service
	Section 3: - Divided into 2 sub-headings that are: 1. About facilities, 3 questions and 2. About serviced received, 13 questions
Section 3: There were 5 questions.	Section 4: Deleted Q5, arranged the layout and added a question about programme recommendation (Q4)
Section 4: There were 11 questions.	Section 5: - Deleted Q10 so there are 10 questions - Arranged the band of household income and words in Q4, Q6 and Q10
Other changes: Number had been written in box of weight and height only	Other changes: - Questionnaire booklet: Had cover page with instruction, date of sending out and names of research team - Given an example on how to write weight and height in the box given so that respondents can follow easily

*Q = Question

5.4 Discussion

5.4.1 Main findings

The self-complete questionnaire was developed by reviewing the literature concerned with evaluating health services in the UK and clients' views towards weight management services. This was followed by discussions within the research team and with Boots staff, both in store and at head office between May and December 2010. More than 70% of pharmacists reported that the questionnaire was relevant, rational, sequential, comprehensive and had a good layout.

The questionnaire was planned to be distributed to clients who were participating in the Boots Pharmacy Weight Loss Programme as a pilot study. However, the total number of clients participating in the BPWLP decreased from 2,847 customers per year in March 2010[199] to 427 clients per year in March 2011.[200]

The pilot questionnaire was approved by Boots and the agreement for the study was in place in April 2011. Using the annual BPWLP reports, the total number of clients across the country who attended the programme between March 2008 and March 2011 was 20,195.[199-201] The number of clients who started the programme during each financial year and remaining in the programme by March were 64%, 28% and 4% in 2009,[201] 2010[199] and 2011,[200] respectively. The total number of clients remaining in the programme by March 2011 was 427 and of those 65 had a planned follow-up after March 2011 across 13 stores.[200] Therefore, it was decided that the plan to request that pharmacist handed the questionnaire to clients attending the programme was not viable as there were so few clients across the stores. The

questionnaire could have been piloted with these 65 clients; however given the reduced attendance at the programme it was felt that a wider survey that was representative of clients attending the programme would not be possible. In order to carry out the pilot study, many of potential participants for the wider survey would need to be used limiting the size of the main survey.

Other methods of distributing the questionnaire, such as a retrospective survey, were considered but it was felt that it would not be possible to achieve a reasonable sample size for analysis. A retrospective postal survey to previous clients was not possible due to lack of access to clients contact details – when they attended the service, they did not sign up to further contact from Boots or for research. Additionally, a retrospective survey would mean that potentially several months would have passed since the clients attended the programme and therefore such a survey would be likely to have problems with recall bias. Recall bias occurs where respondents remember only partial details of an experience – the longer clients have been out of the programme, the greater likelihood they would not recall their experiences of the programme correctly.[202] The main reason why clients were no longer attending the BPWLP is likely to have been the launch of OTC orlistat 60 mg in 2009.[185]

Another alternative to replace the questionnaire survey was interviewing current clients; however there were several disadvantages of such interviews, including:

- The potential language barrier, because English is not the researcher's first language; and hence listening and responding appropriately would be harder than for a native English speaker. Also the researcher might miss some of the

more subtle parts of the conversation which would affect both the interviews and interpretations of the transcribed interviews.

- High travelling expenses as the 65 clients were located across England, Wales and Scotland.
- Recruitment to the interviews would have relied on store pharmacists asking clients to participate. This would be an additional task to add in to consultation and therefore recruitment rates were likely to be low to pharmacists forgetting to ask for permission as this would not be a priority for them in the consultation.
- Clients attended the programme at one or three monthly intervals and therefore recruitment would need to take place over several months.

5.4.2 Strengths and limitations

5.4.1.1 Strengths

The customer questionnaire provided a general measure of clients' views. The main strength of this questionnaire lies in that it was developed with reference to the literature and discussions with supervisors and Boots staff, both from Head Office and pharmacists providing the service. Moreover, testing the questionnaire used face validity judgements from Boots pharmacists and non-Boots pharmacists. Testing for face validity was assessed the relevant questionnaire in terms of the related content, clarity and format. Additionally, the sequence of questions was checked in order to establish whether or not it was easier for clients to complete and to feel more at ease with the same format questions.

5.4.1.2 Limitations

The customer questionnaire was limited to, and only intended to be used with, clients of the BPWLP, and only three Boots pharmacists commented on the questionnaire.

5.5 Summary

A questionnaire was developed and tested to evaluate clients' view about BPWLP. The questionnaire was tested for face validity and sequence of questions by experts. The testing resulted in a number of amendments to the questionnaire. Regrettably, this survey was not carried out due to insufficient numbers of clients participating in the programme, rendering the sample size insufficient. However, it is anticipated that the questionnaire would be useful for use with clients on any other weight loss programmes provided by Boots.

Chapter 6

Discussion

The thesis describes two studies: 1) a systematic review of the literature relating to CWLPs and 2) an evaluation of a commercial weight loss programme. This chapter summarises the findings from each study about the effectiveness of CWLPs on weight loss and discusses the practical implications in terms of health care professional support, policy and strengths and limitations of the study. Finally there are recommendations for future study.

6.1 Key findings

There is little evidence from the UK about the effectiveness of CWLPs; in particular whether this type of programme could help overweight and obese people to lose weight. Characteristics of overweight and obese people who participated in CWLPs were mainly women and aged between 40 and 51 years with a mean BMI between 30 kg/m^2 and 34.5 kg/m^2 at baseline (obesity class I).

The systematic review found three important elements of effective CWLPs: calorie restriction, exercise and support. For a 12-week treatment,[119, 147] participants in the CWLPs achieved a mean weight loss within the range of 3.3 kg (3.6%)[17] to 12.7 kg (13.7%),[146] whilst those in the BPWLP lost 5.8 kg (6.4%). It was found that a meaningful weight loss, which is weight loss of at least 5% of the initial weight, could only be achieved with restriction in total calorie level intake per day and daily

exercise. Meanwhile, support in weight loss interventions in the review were mainly led by health care professionals, such as dieticians, physicians or pharmacists.

The BPWLP involved a private PGD to supply orlistat, together with diet and exercise advice. This programme found 62% of clients who remained in the programme at three months achieved at least a 5% reduction from their initial weight – this meets the NICE guidance on management of overweight and obese adults.[15]

The findings are further discussed below in four topic areas: calorie restriction, exercise, support and medicine.

6.1.1 Calorie restriction

Clients who were put on a very low-calorie diet (<800 kcal/day) can lose 9.5% and 12.3% of the initial body weight up to and for more than three months respectively.[119] This type of diet has a high ability to initiate rapid weight loss so that it is appropriate for obese adults with BMI $\geq$ 30 kg/m^2. This is perhaps the preferred methods, if the clients can tolerate this. However, when this programme is prescribed for obese adults with comorbid health risks, they should be placed under medical supervision. This is because a very low-calorie diet can create a negative water balance in participants. Therefore, it is necessary for the health care providers to closely administer this diet for a reasonable length of time, which is approximately 12 to 16 weeks.[114]

Another type of calorie restriction is to put clients on a low-calorie diet (800-1,200 kcal/day). The systematic review shows that a combination of meal replacement (HMR), calorie restriction of 1,200 kcal/day, exercise up to 2,000 kcal/week and weekly support by a health care provider can produce a weight loss of 13.7%[146] and 13.9%[144] of the baseline body weight for up to or more than three months, respectively.

Considering calorie restriction with energy intake ≥1,200 kcal/day, the two effective weight loss programmes in the review were JC[154] (8.9%) and VTrim[148] (8.9%). Participants in the programmes had restricted diets, with JC providing their own pre-packaged meals and in VTrim by reducing energy intake by daily exercise of up to 1,000 kcal/day. However, the BPWLP did not specify calorie intake but simply advised clients to adopt a low-fat diet as a part of their everyday habit.[99]

6.1.2 Exercise

The systematic review suggests that effective CWLPs should specify a target amount of calories to be burned, such as through daily exercise, of up to 1,000 kcal/day.[148] However, older clients may require different types of exercise due to limitations imposed by their age and health conditions.[147] For instance, younger overweight or obese adults can exercise up to 1,000 kcal per day whilst older overweight or obese adults can adhere to a daily exercise routine by walking 30-60 minutes only.[147]

In the BPWLP, clients were advised to take exercise as a part of their routine in their daily life.[99] However, this programme does not require exercise to be a chore. Clients can find activities suitable to them to burn their calories. Also, this can be done in any location convenient to clients.

6.1.3 Support

Support is another element in weight loss interventions, which is mainly provided by health care professionals[17, 113, 117, 119, 126, 144-147, 153-155, 157] (such as dieticians or physicians) and included counselling, giving advice, encouraging and motivating overweight or obese clients to lose weight. For example, overweight or obese adults who have a very low-calorie diet (<600 kcal/day) need health care providers advice[119] because this diet can create a negative water balance in clients so that this diet needs to be closely administer for a reasonable length of time (12-16 weeks).[114]

Counselling for BPWLP clients is provided by pharmacists during the monthly visit, which includes comprehensive support and advice on healthy eating and physical activity.

6.1.4 Medicine

Pharmacotherapy is the second-line treatment for obesity.[16] The study presented in this thesis conducted an assessment of the effectiveness of a pharmacist-led weight management clinic in the UK, which focused on the use of orlistat 120 mg, in combination with advice on diet and exercise. The key findings show that mean

weight loss through a BPWLP was 6.4% of the initial body weight, whilst mean weight loss noted in the systematic review ranged from 3.6% to 13.7% of the initial body weight for a 12-week treatment. The mean weight loss in the BPWLP was the same range that achieved by participants in another orlistat study, which reported a weight loss between 6-10%.[75]

6.2 General discussion

There are two categories of weight loss intervention reviewed in this study: primary and secondary. Primary weight loss intervention consists of three potential elements: calorie restrictive diet, exercise and behavioural or psychological support by health care professionals. However, if clients failed to achieve their weight loss goal of at least 5% of their initial weight, a secondary intervention could be used; an anti-obesity medicine.

In comparing this systematic review of CWLPs, the previous review of pharmacy-based weight loss programmes[18] and the BPWLP, two key areas are discussed – amount of weight lost and dropout rates. In the BPWLP, mean weight loss was -5.8 kg whilst mean weight change in the systematic review of CWLPs showed a range from -3.3 to -12.7 kg at 12 weeks. A study that focused on retention in a weight loss programme[182] reported a weight change of -7.5 kg (8.3%) at 13 weeks, which was in the range of the current review but greater than the BPWLP. Gordon et al.[18] in their systematic review of community pharmacy-based weight management programmes included only NCWLPs and found a mean weight change from -4.9 to -5.6 kg at either three or six months. A more recent RCT in the UK included a non-commercial

pharmacy arm where they found a mean weight loss of -2.1 kg at 12 weeks.[17] Therefore, mean weight loss for clients who attended the BPWLP was similar to that found in the literature for weight loss in short-term.

The systematic review showed that successful weight loss interventions for short- and long-term treatment had dropout rates ranging from 0% to 54% and 11% to 49%, respectively. The dropout rate in the BPWLP (70%) at 12 weeks was higher than the dropout rate in the current review and the study by Finley et al.[182] (58%) at 13 weeks. Gordon and colleagues study[18] of non-commercial pharmacy-based programmes found dropout rates between 31% and 52% over periods of 6-24 months. It is perhaps surprising that when clients spend their own money on a weight loss programme that they do not remain in the programme longer. Possible reasons for the higher dropout rate may be that each visit in a CWLP costs money, that when clients achieve their desire weight loss, they do not feel they need to return for another visit or they are dissatisfied with the programme and its effect on their weight loss and therefore do not return.

There are several reasons for attrition, deduced from the findings, including difficulty of keeping to a very low-calorie daily diet, meeting weight loss goals or failure to lose weight. Nevertheless, there are many possible reasons behind success or failure, including levels of motivation to achieve the desired weight loss, both positive and negative personal circumstances and dissatisfaction with side-effects. To reduce the dropout rate, support from health care providers should be encouraging, aimed at motivating clients to stay in the programmes longer, particularly is related to the accompanying positive health benefits.

The number of adverse events reported in the CWLPs and BPWLP was lower than in other studies.[176, 178] Only Anderson and colleagues[144] study reported adverse events in terms of dietary problems and constipation. For the BPWLP, this programme found adverse events were mainly related to gastrointestinal issues. The most common adverse events were loose stools, diarrhoea, constipation, stomach ache or headache. In CWLPs, therefore, the fewer number of adverse events reported, the more likely it is that people will pay for attending the programme.

6.3 Practical implications

6.3.1 Weight loss programmes supported by health care professionals

The systematic review shows that CWLPs can be effective in achieving weight loss. Health care professionals need to be aware that commercial programmes are effective and which of these are offered in the local area to better advise their clients about losing weight and the help available to support overweight and obese people.

Health care professionals can help overweight or obese people to lose weight by counselling their clients. They support their clients in terms of diet and exercise advice. This study indicated that weight loss interventions which contain health care professionals' support are more likely to achieve clinically significant weight losses. However, Jolly and colleagues[17] study showed that CWLPs arms such as WW (4.7%), SW (3.8%) and RC (4.5%) had greater weight loss than NCWLPs arms of GP (1.5%) and pharmacy (2.3%). Therefore, it is reasonable to suggest that relevant health care professionals in the CWLPs, such as physicians/general practitioners

(GPs) and pharmacists, can enhance weight loss in overweight or obese people who attend the programme.

A number of CWLPs have been shown to be effective in terms of weight lost.[117, 119, 124, 126, 144, 146-148, 151-155] However, it is not known how these programmes compared with each other in term of effectiveness as it is not possible to be sure that the control arms are sufficiently similar. A range of weight loss strategies will allow clients to select a programme which they feel is possible for them to adhere to over several months or years.

The systematic review found that effective CWLPs included a number of elements – daily calorie restriction, daily exercise and support (in the reviews this was mainly led by physicians or GPs). These elements match the first line strategy for obesity treatment in the NICE guideline, as did the target of 5% weight loss over three months being seen as a suitable amount which would benefit health.[15] Second line obesity treatment recommended by NICE combines the first line treatment with anti-obesity medicine, as in the BPWLP.

6.3.1.1 General practitioners

In this study, health care providers who are part of the support structure in the CWLP are sometimes physicians or GPs, demonstrating, they can play a role in obesity treatment by doing some or all of the following:[93]

- Be aware of and active in identifying patients:[69]
    - Who are visibly overweight or obese.

  - With health risks or conditions affecting weight loss, such as cardiovascular disease, diabetes, hypertension or joint disorder.
  - Where patients want to lose weight.
  - Where previous weight loss attempts have not been successful.

- Talk with patients about health problems; inform them about health benefits and other reasons for losing weight. For example, physicians in one study[11] administered diet-specific advice to each intervention. Physicians revealed the important information, provided the rationale and positively reinforced dietary changes to maximise adherence to the weight loss programme.
- Increase motivation by clarifying with patients:[69]
  - What their realistic and achievable weight loss goals are.
  - How to modify their lifestyle to integrate regular physical activity for enhancing cardiovascular health and individual weight status. For example, participants in meal replacement programmes[144, 146] were encouraged to record the number of meal replacements and the calories burned in physical activity.
  - The likely health benefits resulting from their weight loss.
  - Advise on the comparable cost of CWLPs.
- Advise by providing:
  - Relevant counselling about weight loss and its outcomes alongside information and resources for patients to access.[203]
  - Lifestyle prescriptions such as portion control consultation. For example, dieticians can help patients to devise suitable menus for specific diets such as a low-carbohydrate/high-protein diet (LCHP)[119] as an alternative to doctors prescribing medication.

  - Self help materials. For example, diet assignments, exercise strategies[114] and information about barriers and facilitators of weight change. Additionally, details of factors associated with greater or lesser weight change and components of interventions associated with the effective health-related behaviour change[161] and also the difficulty of weight loss.[69]

- Develop appropriate weight loss interventions based on patients' willingness to change, such as:
  - Asking patients to keep a food and exercise diary, and reviewing this when they attend the programme and tailoring their advice based on the diary.
  - Learning about the principles of obesity management including behavioural change techniques and promotion of increase exercise levels.[204]
- Ensure that patients understand the benefits of taking medications to control health conditions. For instance, clients in the BPWLP who were taking medicines prescribed by their doctors should record all generic names of medicines taken. The reason is that all medicines taken should not affect weight gain.
- Prescribing and referral:
  - Prescribing pharmacotherapy where appropriate.
  - Referring to dieticians, exercise physiologists or psychologists if needed. GPs support in the weight loss programmes may not necessarily enhance patients' attendance to the CWLPs. This evidence was found in the GP programme[17] with the high dropout rate (54%).

However, GPs should focus primarily on clients' psychological needs, because obesity is also a social issue. For instance, physicians should work with dieticians[11, 17, 126, 145, 150-152, 156] as a team to encourage participants to change clients' behaviour in a positive direction by giving advice and attention to such issues as healthy eating, increasing daily activity, promoting healthy lifestyle and providing written educational materials if the clients are on the CWLPs.

Therefore, GPs' involvement may build confidence and trust with the clients, which may improve their weight change over time.

6.3.1.2 Pharmacists

This study reported the successful implementation of a weight management clinic led by community pharmacists. Pharmacists in the BPWLP provided orlistat, guidelines for calorie restriction and exercise, and monthly counselling. Therefore, these multiple roles may be recommended for future services offered by community pharmacists. However, this role can be expanded in order to maximise the effectiveness of BPWLP and minimise the attrition rate.

Pharmacists in the BPWLP can enhance clients' reduction in weight and reduce the dropout rate by:

- Providing safe supply of orlistat:
    - Warning about adverse effects and drug interactions.

  - Identifying and monitoring appropriate individuals to use weight-loss medicines to maximise safety and efficacy.

- Recording clients' comments and adverse events in the consultation notes at monthly and three monthly visits.
- Appropriate counselling in terms of the client's healthy eating, increasing daily exercise and medicines use.
- At follow-up visits where clients have co-morbid health risks from their chronic disease, pharmacists should review orlistat treatment in the light of any changes in their medications (prescribed or purchased OTC) and general health.[168]
- The procedures for BPWLP did not require recording of co-morbid conditions in clients whose BMI $\geq$ 30 kg/m^2. If pharmacists' advice is to be tailored to individual clients needs, understanding the complete picture of clients health is needed. However, pharmacists should only have records on what is needed to provide their services and some may feel weight management service can be provided without pharmacists' knowledge of clients' co-morbid conditions.
- Providing information for clients in terms of making referrals if necessary, for example having high blood pressure or excessive blood glucose levels. Clients should consult with their doctors and display doctor's confirmation to pharmacists as to whether or not clients are able to continue or discontinue the programme.

- Communicating with clients about the health advantages of losing weight and collaborating with other health care professionals.
- Motivating clients' changes for their lifestyle to improve and maintain weight loss.
- Providing advice and pro-active support by telephone contact to improve the success of weight loss and maintenance efforts.
- Reminding clients' weight targets – at least 5% weight loss at 12 weeks.

Although the BPWLP was withdrawn in September 2012, this programme supported overweight or obese clients to lose weight by providing a combination of orlistat 120 mg supply with advice and support about diet and physical activity. However, there is still insufficient evidence in terms of weight management interventions in the community pharmacy setting, to offer unequivocal support to the CWLPs. Despite this being a setting which could be an ideal venue for weight loss programmes due to the convenience of access and long opening hours. This could be an ideal public health service for pharmacies to provide as part of their contribution to tackling health problems in their local authority area.

Pharmacists could improve weight loss and reduce the dropout rates in CWLPs such as MR or conventional reduce-calorie diet (RCD)[205] programme by:[206, 207]

- Learning all the necessary skills to facilitate weight loss interventions, such as taking the relevant measurements (weight, BMI and waist circumference) and motivational interviewing.

- Understanding the wider aspects of clients' weight loss goals:
    - How to approach and support clients to improve their weight loss; providing information on diet, exercise, lifestyle and current habits; advising them in terms of energy intake and energy expenditure; and facilitating diet programmes, for example, VLCD, LCD or meal replacement.
    - Learning to be comfortable in the conversations with overweight and obese people.
    - Understanding and being empathetic about clients' difficulties with losing weight.
    - Providing weight loss services in their community pharmacy.
- Being clear about their role as health care professionals rather than retailers or shopkeepers. Orlistat 60 mg (Alli®) is available for OTC supply in the pharmacy, but must be supervised by a registered pharmacist.[85, 110] This OTC weight loss product is effective when used in combination with a reduced-calorie, low-fat diet and exercise programme. However like other medicines, anti-obesity medicines are not just a product and should only be sold after a consultation with the clients and with appropriate advice.
- Collaborating with other health care professionals in terms of:
    - Integrating into the primary care team and developing good relationships.
    - Coordinating with multi-disciplinary teams, such as GPs and dieticians in order to offer better weight management services.

- Being proactive in developing their professional role:
    - Help clients to feel more confident by taking the time needed in consultations.
    - Be trustworthy, skilful and knowledgeable in the weight management services they provide. For example, Wollner and colleagues study[208] showed effective weight loss could be achieved in their convenience care clinic which was based in pharmacies. They also showed that this CWLP could increase market share in a pharmacy setting with the additional benefit of monitoring co-morbidities associated with obesity.

With the increasing numbers of overweight and obese UK adults, effective weight loss interventions are needed that are designed to be easier for clients to manage. Drug treatment is a suitable second step for obese people who are unable to lose weight by using a combination of diet, exercise and lifestyle modification. As a member of the health care professional team, pharmacists should encourage people to control their weight and to maintain a healthy weight in everyday life. This includes providing weight management services for overweight and obese people.

6.3.2 Policy

This study suggests that CWLPs are effective in helping overweight and obese people to achieve their weight loss goals and to become healthier. Public health policy should reflect the place of CWLPs as well as health services in developing and implementing weight loss interventions. Public health authorities should offer a

range of options for dietary restriction, appropriate exercise regimens and support from both professionals and self-help groups in providing affordable and accessible weight loss programmes so that individuals can choose the programme they feel is most likely to be successful. Such weight loss strategy should include action at local and national levels if it is to achieve a significant reduction in population health risks related to obesity.

The review found three key elements (calorie restriction, exercise and support) in the CWLPs that were essential factors in weight loss. For those who are not successful in their initial attempts to lose weight a further option in obesity treatment is anti-obesity medicine, which should be offered where appropriate as a second line treatment. Therefore, the NHS should ensure that such elements are included in public weight loss programmes.

The CWLPs could help UK government's plans for tackling obesity in terms of building the evidence base about the effectiveness of CWLPs in order to promote the spread of good practice and full use of evidence.[209] The commercial programme can deal with overweight or obese problems among people who are willing and able to pay for the programme.

This study proposes three crucial components of the CWLPs for the policy makers to attend to: calorie restriction, exercise and support. This component should be combined in a structured programme and typical element would be:

1. Promotion of healthy food intake with guideline daily amounts (GDA) by the creation of healthy food environments related to food and nutrition policy in

obesity treatment[210] such as a portion controlled diet plans (calorie controlled for all foods in women with 1,250 kcal/day and men with 1,550 kcal/day),[147] carbohydrate or fat restriction,[11, 117] macronutrient balance (40% carbohydrate, 30% fat, 30% protein),[11, 117] The LEARN Manual for Weight Management (55-60% carbohydrate, 10% fat)[117] and balanced diets.[17]

2. Choose the suitable options for obese people such as:
    a. A very low-calorie diet (<600 kcal/day) intake, which does not specify requirement for exercise. However, medical supervision is needed.
    b. A low-calorie diet (800-1,200 kcal/day) with daily exercise, which requires weekly support from health care professionals.
    c. For clients who meet the NICE guideline for receiving anti-obesity medicines, they should receive such medicine with non-pharmacotherapy for obesity treatment, as above, and should be supported by members of a health care professional team, such as dieticians, physicians and pharmacists.
3. Specify the appropriate exercise to target amount of calories to be burned and attempt to encourage exercise as an activity of everyday life. For example, local authorities could set exercise standards and guideline to create environments that promote exercise such as walking,[147] running and jogging,[211] cycling[210] and swimming.[211]
4. Provide counselling to overweight or obese people about their eating habits and personal habits by[210]
    a. Monitoring their weight and health risks associated with obesity.

b. Communicating up-to-date information about healthy eating and exercise.

c. Motivating patients to adopt healthy lifestyles with consistent information.

5. A multidisciplinary team comprising qualified counsellors and health care professionals such as registered dieticians, doctors and pharmacists should

   a. Be involved to help patients achieve their weight loss goals.[11, 17]

   b. Develop clinical governance processes for the care of overweight and obese people.

   c. Support obesity research by any organisations, public or private sector carrying out high quality research.[210]

6.3.3 Strengths and limitations of the study

6.3.3.1 Strengths

The systematic review has identified the important components of weight loss programmes that enable the achievement of meaningful weight loss. The evidence from the systematic review and the retrospective study suggests the need for researchers to think similarly about options in obesity treatment. This is the first systematic review of literature from across the world rather than being restricted to particular countries. This provides valuable up-to-date evidence of the CWLPs.

Moreover, a pharmacist-led weight management intervention primarily evaluates through a combination of orlistat supply and advice in the UK. This study not only has examined the efficacy of CWLPs in a variety of settings such as primary and

secondary care settings, including community settings but also has been supported the programmes by health care and non-health care providers to offer competent professional advice to the programme's clients. Therefore, the evidence in this study shows a good combination of a first and a second line treatment in obesity. The systematic review of CWLPs demonstrates the effectiveness of the first line treatment whilst the retrospective study of BPWLP shows the effectiveness of the second line treatment in obesity.

6.3.3.2 Limitations

There are several limitations to the work presented in this thesis. Firstly, this study only investigated the effectiveness of the CWLPs. Therefore, the population in this study is confined to overweight and obese adults who are willing and able to pay in order to attend their weight loss programmes. As a result, overweight or obese people who cannot afford to join a private health care service have been excluded from this study; this study's findings cannot therefore be generalised to NCWLPs.

Secondly, this study is based on a secondary analysis of the published literature between 1980 and 2011, combined with data from the records of the BPWLP. The results were only from studies that conformed to the inclusion criteria related to the CWLPs, such as a structured programme and organisation delivering intervention for profit organisation.

Thirdly, by the time the questionnaire was approved, there were insufficient numbers of clients participating in the BPWLP so that the planned research initiative based on

the customer questionnaire was not carried out. The questionnaire was designed to evaluate clients' views of the BPWLP in terms of experiences of programme, medicine, and other weight loss programmes and activities. Therefore, the questionnaire is limited in that it is designed for a specific group of clients.

Lastly, this study focuses solely on weight loss outcome in overweight and obese adults. Therefore, other outcomes such as weight maintenance, factors related to obesity and cost-effectiveness are unknown. In particular, BPWLP's clients reported factors related to comorbid health risks, which was a requirement for clients to report their comorbid health risks on the customer record forms, whilst pharmacists recorded side effects, which may be less reported on the consultation notes. Also, the level of accuracy of the records made by the pharmacists during the consultation is not known.

6.4 Recommendations for further study

Further study is warranted in order to gain knowledge relating to retention rates and to focus on the factors which contribute to long-term treatment and weight maintenance of participants. It is also suggested that a direct comparison be made between commercial and non-commercial weight loss programmes in terms of cost-effectiveness. This can be achieved by conducting a RCT. The advantage of using a RCT is that it can reduce bias by minimising allocation and balancing both known and unknown confounding factors.[212] Moreover, more support from providers should be recommended. This may help to reduce the dropout rate during the trials, which is one factor which is related to judging the effectiveness of CWLPs.

A questionnaire survey can also be undertaken with overweight or obese people who attend the CWLPs. This may help to explore the patients' experience of the CWLPs, weight loss service, use of diet; exercise; support and/or medicine, and demographics of respondents. This will shed light on patient satisfaction, facilitators and barriers to losing weight.

In addition, this study did not investigate the effectiveness of unstructured CWLPs such as OTC weight loss products and orlistat 60 mg. Further research would be needed to evaluate these services and their clinical outcomes. It would be interesting to assess by comparing other CWLPs and/or pharmacy medicine with usual or standard care in order to ensure whether such weight loss programmes are more or less effective in helping overweight and obese people to achieve meaningful weight loss, at least 5% of their initial weight.

6.5 Summary

This thesis has evaluated the effectiveness of CWLPs by systematically reviewing literature and determining the effectiveness of the BPWLP in order to propose which elements are most effective in CWLPs. Three elements, those of calorie restriction, exercise and support are currently insufficient evidence for CWLPs in the UK to support clients' decisions in choosing which CWLP is appropriate for them. Therefore, more research is needed to strengthen this evidence base for CWLPs.

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Appendices

Appendix 1 Boots PGD for the supply of orlistat

Table A1.1 Patient Group Direction (PGD) for the supply of orlistat

Name of authorising body	Boots IMA
PGD comes into effect	01-09-2008
PGD expires	31-08-2010
Supply and legal classification	Orlistat will be supplied as 120 mg hard capsules in blister packs containing 84 capsules. Legal classification POM The capsule is presented as turquoise cap and turquoise body bearing the imprint of "ROCHE XENICAL 120"
Class of health professional who supply orlistat	Royal Pharmaceutical Society of Great Britain (RPSGB) registered pharmacists who are authorised to provide the Boots Pharmacy Weight Loss Programme (BPWLP) and who have received training and been authorised to supply orlistat under this PGD.
Supply outside the terms of the summary of product characteristics (SPC)	Orlistat may not be supplied outside the terms of the SPC.
Clinical situation for which medicine is to be used	Orlistat is indicated in conjunction with a nutritionally balanced, mildly hypocaloric diet for the treatment of the following groups of patients: - Patients who are obese (BMI $\geq$ 30 kg/m^2), are actively participating in a weight management programme and have demonstrated motivation to change dietary behaviour. - Patients who are overweight (BMI $\geq$ 28 kg/m^2 but < 30 kg/m^2), with at least one associated risk factor/co-morbidity (such as cholesterol > 5.2 mmol/L, high blood pressure, any heart disease, non insulin-dependent diabetes mellitus, chronic respiratory disease including asthma and chronic obstructive pulmonary disease (COPD), arthritis of a weight bearing joint such as hip/knee/ankle, gastro-oesophageal reflux disease, hiatus hernia, gall stones, stress incontinence, those on a waiting list for surgery, pituitary disease or any other condition where loss of weight would be medically beneficial). Treatment with orlistat will be discontinued after 12 weeks if patients have been unable to lose at least 5% of the body weight as measured at the start of drug therapy. Treatment may be continued for up to 24 months or until the patient reaches the target weight corresponding to a BMI of 20-25 kg/m^2, as agreed between the patient and pharmacist.

Table A1.1 (continued)

Criteria for inclusion	Patients must be registered with a GP and be willing to accept treatment from a pharmacist. - All patients will have their height, weight, BP and random blood sugar measured in the pharmacy. - BMI $\geq$ 28 kg/m^2 but < 30 kg/m^2 with at least one associated risk factor/ co-morbidity as described above - BMI $\geq$ 30 kg/m^2 with or without associated risk factors - Age 18-82 years, inclusive - Informed verbal consent to treatment and adherence to appropriate dietary intake - Consent to inform GP of relevant clinical detail including treatment with orlistat under the PGD
Criteria for exclusion	- BMI < 28 kg/m^2 - Age under 18 years and 83 years or older - Refusal of consent - Known hypersensitivity to orlistat - Current cholestasis - Breast feeding or pregnancy - Concurrent administration of ciclosporin, acarbose, amiodarone, sibutramine or other weight loss agents and insulin - Chronic malabsorption syndrome - Weight management surgery - Insulin dependent diabetes mellitus Patients not eligible for treatment under this direction will be given weight management advice and recommended to consult their GP for further assessment, where appropriate.
Criteria for referral	Patients should be referred to their GP: - When patient is considered eligible for orlistat therapy under a weight loss programme, but supply through pharmacy is excluded by the PGD. This might include any of the conditions referred to as exclusion criteria above and also: - Previously unrecognised co-morbidities: BP > 140/90 mmHg Random blood glucose exceeding 5.6 mmol/L - Uncontrolled symptoms of other illnesses that are a cause for concern e.g. mental health, orthopaedic problems
Dosage and method of administration	The recommended dose of orlistat is one 120 mg capsule which should be taken with water immediately before, during or up to one hour after each main meal (2-3 times daily). If a meal is missed or contained no fat, the dose of orlistat should be omitted.

Table A1.1 (continued)

Period of administration	This will be determined by the pharmacist but will normally follow the following guidelines: - Treatment with orlistat will be discontinued: After 12 weeks if patients have been unable to lose at least 5% of the body weight as measured at the start of drug therapy If patients fail to achieve adequate to continuing weight reduction. Most patients will be an average of 0.5 to 1 lb weight loss per week. - Treatment with orlistat may be continued up to 24 months or until the target weight is reached corresponding to a BMI of 20-25 kg/m2, as agreed between the patient and pharmacist.
Drug interactions	The concomitant administration of orlistat is not recommended with the following: 1) Acarbose, 2) Anorectic drugs, 3) Amiodarone, 4) Ciclosporin Administration in patients taking warfarin or other anticoagulants requires International Normalised Ratio (INR) values to be monitored. Therefore these patients should be referred to the GP for INR monitoring. Whilst there is not an interaction with oral contraceptives, orlistat may indirectly reduce the availability of oral contraceptives and lead to unexpected pregnancies in some individual cases. An additional contraceptive method is recommended in case of severe diarrhoea.
Side effects	The most frequent adverse reactions to orlistat are largely gastrointestinal in nature: - Oily spotting from rectum - Flatus with discharge - Faecal urgency - Fatty/oily stool - Oily evacuation - Increased defecation - Faecal incontinence The patient information leaflet will include detail of adverse events associated with orlistat, and the patient is asked to read this.

Table A1.1 (continued)

Advice to patient	The advice to patients will include specific product advice, in addition to general advice relating to physical activity and diet: - Orlistat must be taken with recommended healthy balanced diet containing less than 30% energy (calories) from fat. - 1 x 120 mg capsule orlistat should be taken immediately before, during or up to one hour after each main meal (2-3 times daily). - If a meal is missed or contained no fat, the dose of orlistat should be omitted. - The capsule should be stored in a cool place. Recommend that the patient read the appropriate enclosed information leaflet which should be given to the patient at the time of supply. This gives details of how to take orlistat and how to modify dietary intake appropriately.
Follow-up	Follow-up appointments should be made at the end of month 1, 3, 6, 12, 18 and 24. BMI should be assessed at each follow-up appointment.
Adverse outcomes	Patients must be advised to follow a healthy balanced dietary intake containing less than 30% of energy (calories) from fat while taking orlistat. If the caloric intake exceeds 30% of energy (calories) from fat, patients may experience gastrointestinal side effects such as: - Oily spotting from rectum - Flatus with discharge - Faecal urgency - Fatty/oily stool - Oily evacuation - Increased defecation - Faecal incontinence Patients should be advised about the time of dispensing orlistat and a balanced diet with appropriate fat intake. These treatment effects can be managed and are less to occur. Any event of this mature suggests that the dietary intake has been inappropriate and may reflect hidden fat in the diet. This possibility can be alerted to the patient. Patients should be able to modify their dietary intake appropriately to avoid these treatment effects. Pharmacists will make a record of suspected adverse reactions to orlistat which will be reported to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card scheme.

Table A1.1 (continued)

Facilities and supplies	Orlistat should be stored in a cool place. Orlistat, when issued, is to be labelled with the date of dispensing and the patient's name, according to pharmacy procedures on the patient medication record system. A mechanism will be put in place to ensure that the patient record acknowledges the supply of orlistat under PGD.
Management and monitoring	Patients need to be registered with the authorised pharmacy where treatment is provided for supply of medicines under a private PGD. The pharmacist will record and retain patient details including name, address, date of birth (DOB), sex, telephone number and the GP name and contact details. At each follow-up consultation, the pharmacist will review adherence to the dosage regimen, the development of any side effects, any changes to concomitant diseases or medicines and confirm that there is adequate to continuing weight loss.
Informed consent	Patient information relating to the supply of orlistat under PGD will be kept confidential. Individual information regarding the patient's care will be shared with the patient's GP. Anonymised information, collected for the purpose of clinical audit may be shared with other bodies such as regulatory agencies of the orlistat marketing authorisation holder, with the written consent of the patient.
Details of record keeping for audit purposes	The pharmacist must keep a record for each consultation, in accordance with care standards guidelines. This record will be timed and dated and signed by the pharmacist with their designation. Records will be securely retained in accordance with minimum care standard guidelines.
Characteristics of staff authorised to take responsibility for supply and administration	Member of the RPSGB and a practising community pharmacist Have undergone training an weight management and the PGD, including the self-directed learning package on administration or orlistat, and received authorisation to provide this service by the IMA

Appendix 2 Search strategies for database and terms

Table A2.1 Search strategies for database and terms for Medline, EMBASE, PsycInfo, HMIC and IPA

Database	Search strategies	Results
Medline	Population	Medline: 165046
EMBASE	1. overweight.tw.	EMBASE: 234636
PsycInfo	2. obes$.tw.	PsycInfo: 20924
HMIC	3. exp morbid obesity/ or obesity.mp.	HMIC: 3179
IPA	4. or/1-3	IPA: 2819
	Intervention/Comparison	Medline: 1329856
	5. commercial$.tw.	EMBASE: 1713175
	6. (commercial adj7 program$).tw.	PsycInfo: 188737
	7. (weight adj5 program$).tw.	HMIC: 23789
	8. (weight adj5 product$).tw.	IPA: 173839
	9. diet$.tw.	
	10. supplement$.tw.	
	11. meal replacement.tw.	
	12. exercise.tw.	
	13. physical activ$.tw.	
	14. antiobesity agent$.tw.	
	15. pharmacotherapy.tw.	
	16. drug therapy.tw.	
	17. physician$.tw.	
	18. pharmac$.tw.	
	19. usual care.tw.	
	20. standard care.tw.	
	21. proprietary.tw.	
	22. or/5-21	
	Outcomes	Medline: 118564
	23. weight loss.tw.	EMBASE: 153680
	24. weight control.tw.	PsycInfo: 16742
	25. weight reduction.tw.	HMIC: 1574
	26. weight management.tw.	IPA: 2994
	27. weight change$.tw.	
	28. body mass index.tw.	
	29. or/22-28	

Table A2.1 (continued)

Database	Search strategies	Results
Medline	Studies	Medline: 2101710
EMBASE	30. randomi$ control$ trial.tw.	EMBASE: 2576506
PsycInfo	31. controlled clinical trial.tw.	PsycInfo: 391247
HMIC	32. clinical trial$.tw.	HMIC: 26889
IPA	33. random$.tw.	IPA: 91913
	34. control.tw.	
	35. time series.tw.	
	36. controlled before and after.tw.	
	37. uncontrolled before and after.tw.	
	38. cohort$.tw.	
	39. or/30-38	
	40. 4 and 22 and 29 and 39	Medline: 4442
	41. limit 38 to	EMBASE: 4594
	Medline: (english language and humans and yr="1980 - 2011" and "all adult (19 plus years)")	PsycInfo: 999
	EMBASE: (humans and english language and yr="1980 - 2011" and (adult <18 to 64 years> or aged <65+ years))	HMIC: 193
	PsycInfo: (human and english language and adulthood <18+ years> and yr="1980 - 2011")	IPA: 206
	HMIC: yr="1980 - 2011"	
	IPA: (english language and human and yr="1980 - 2011")	
	42. remove duplicates from 41	
Results	Medline: 4442	
	EMBASE: 4594	
	PsycInfo: 999	
	HMIC: 193	
	IPA: 206	

Table A2.2 Search strategies for database and terms for CENTRAL and CINAHL

Database	Search strategies	Results
CENTRAL	Population: (Obesity OR Obesity, Morbid) OR Overweight	5834
	Intervention/Comparison: (commercial* or weight loss program* or weight loss product*) OR (Diet OR Dietary Supplements OR meal replacement) OR (Exercise OR physical activ* OR Anti-Obesity Agents OR Drug Therapy OR Physicians OR Pharmacists OR Pharmacy OR Pharmacies) OR (usual care or standard care) OR proprietary	138923
	Outcomes: (Body Weight Changes OR Weight Loss OR Body Mass Index) OR weight control OR weight reduction OR weight management OR weight change*	25143
	Studies: randomi* control* trial OR controlled clinical trial OR clinical trial* OR random* OR control OR time series OR controlled before and after OR uncontrolled before and after OR Cohort Studies	438373
	AND combines all components	2531
	From 1980 to 2011	2492
CINAHL	Population: Obesity or obes* or Overweight	18746
	Intervention/Comparison: (commercial* or weight loss program* or weight loss product*) or (MH "Diet+") OR (MH "Dietitians") OR "diet* or (MH "Dietary Supplements+") OR (MH "Dietary Supplementation") OR "supplement" or "meal replacement" or (MH "Exercise+) OR "exercise" or (MH "Physical Activity") OR "physical activ*" or (MH "Antiobesity Agents+") OR "antiobesity agent*" or (MH "Drug Therapy+") OR "pharmacotherapy" or (MH "Physicians+") OR "physician" or (MH "Pharmacists" OR "pharmac*") or (usual care OR standard care) or "proprietar*"	498513
	Outcomes: (MH "Body Mass Index") OR "body mass index" or weight loss or weight control or weight reduction or weight management or weight change*	39639
	Studies: (MH "Randomised Controlled Trials") OR (MH "Clinical Trials") OR "randomi* control* trial" or controlled clinical trial or random* or control or (MH "Time Series") OR "time series" or controlled before and after or uncontrolled before and after or cohort*	616633
	AND combines all components	1658
	Published Date from: 19800101-20111231; English language; Age Groups: Adult: 19-44 years, Middle Aged: 45-64 years, Aged: 65+ years	909
Results	CENTRAL: 2492	
	CINAHL: 909	

Table A2.3 Search strategies for database and terms for Scopus and WOS

Database	Search strategies	Results
Scopus	(obes* OR mobid* obesity OR overweight) AND ((commercial* OR weight loss program* OR weight loss product*) OR (diet* OR supplement* OR meal replacement) OR (exercise OR physical activ*) OR (antiobesity agents OR drug therapy OR pharmacotherapy OR physician* OR pharmac*) OR (usual care OR standard care) OR (proprietary)) AND (body mass index OR weight loss OR weight control OR weight reduction OR weight management OR weight change*) AND (randomi* control* trial OR controlled clinical trial OR clinical trial* OR random* OR control OR time series OR controlled before and after OR uncontrolled before and after OR cohort*) AND (Limit to (Language "English" AND 1980-2011))	2376
WOS	Population: obes* OR mobid* obesity OR overweight	76546
	Intervention/Comparison: (commercial* OR weight loss program* OR weight loss product*) OR (diet* OR supplement* OR meal replacement) OR (exercise OR physical activ*) OR (antiobesity agents OR drug therapy OR pharmacotherapy OR physician* OR pharmac*) OR (usual care OR standard care) OR proprietar*	582026
	Outcomes: body mass index OR weight loss OR weight control OR weight reduction OR weight management OR weight change*	30025
	Studies: randomi* control* trial OR controlled clinical trial OR clinical trial* OR random* OR control OR time series OR controlled before and after OR uncontrolled before and after OR cohort*	934417
	AND combines all components, Timespan = 1980-2011	145
Results	Scopus: 2376 WOS: 145	

Appendix 3 Data extraction form for full articles

Article identification:	Reviewer's initials: SS	Verifier's initials: HB
Author and year:		Country:
Objectives		
Methods		
Participants	Inclusion criteria:	
	Exclusion criteria:	
	Settings and/or locations:	
	Duration:	
	Recruitment methods :	
	Sample size:	
Study design	Randomization-sequence generation:	
	Allocation concealment:	
	Implementation:	
	Blinding:	
	Statistical methods:	
Intervention		
Comparison/ Control		
Outcomes	Primary and secondary outcome measures	
Results		
Participant flow		
Baseline data	Demographics:	
Number analyzed	Summary data for each intervention group (ITT and/or completers)	
Outcomes and estimation		
Adverse events		
Discussions		
Interpretation	Introduction	
	Methods	
	Assessing outcomes:	
	Provider:	
	Statistical methods:	
	Results	
	Discussion	
Generalisability		
Other evidence	General comments	
Funding		

Appendix 4 Judging risk of bias

Criteria for the risk of bias were identified to assist making judgements about the papers. There are seven domains in this assessment tool which include 1) sequence generation, 2) allocation concealment, 3) blinding of participants and personnel, 4) blinding of outcome assessors, 5) incomplete outcome, 6) selective outcome reporting and 7) other sources of bias.

Reviewers judged for the risk of bias and indicated the each criterion as being ‘low risk’, ‘high risk or ‘unclear risk’. The criteria for judging risk of bias were described in Table A4.1 below.

Table A4.1 Criteria for judging risk of bias

Low risk of bias: Described	High risk of bias: Described	Unclear risk of bias: Described
Sequence generation: Judging for		
A random number of table A computer random number generator Coin tossing Shuffling cards or envelopes Throwing dice Drawing of lots Minimisation: Implemented without a random element and considered to be equivalent to being random	Sequence generated by odd or even date of birth, by some rule based on date or day of admission or by some rule based on hospital or clinic record number Allocated by judgement of the clinician, by preference of the participant or by availability of the intervention Allocation based on results of a laboratory test or a series of tests	Insufficient detail in the sequence generation process to judge either yes or no
Allocation concealment: Judging for		
Participants were enrolled to conceal allocation as: Central allocation includes telephone, web-based and pharmacy-controlled randomisation Sequentially numbered drug containers or opaque sealed envelopes	Participants were enrolled to conceal allocation and introduced selection bias based on using: An open random allocation schedule e.g. a list of random numbers Assignment envelopes used with inappropriate safeguards e.g. unsealed envelopes, non-opaque or not sequentially numbered Alternation or rotation Date of birth Case record number Other unconcealed procedure	Insufficient detail in allocation concealment process to judge either yes or no No description of concealment methods Unclear whether envelopes were sequentially numbered, opaque or sealed
Blinding of participants, personnel and outcome assessors: Judging for		
No blinding, but reviewers judge that outcomes were unlikely to be influenced by lack of blinding Participants' and key study personnel's blinding was certified that blinding is unlikely to be broken. If participants and key study personnel were not blinded, but outcome assessors were blinded, non-blinding of others were unlikely introduced bias.	No blinding or incomplete blinding, and outcomes were likely to be influenced by lack of blinding Participants' and key study personnel's blinding was certified that blinding was likely to be broken. If participants and key study personnel were not blinded, non-blinding of others were unlikely introduced bias.	Insufficient detail to judge either yes or no No description of outcomes

Table A4.1 (continued)

Low risk of bias: Described	High risk of bias: Described	Unclear risk of bias: Described
Incomplete outcome data: Judging for		
No missing outcome data Reasons for missing outcome data were not related to true outcome Missing outcome data balance in numbers across intervention groups with similar reasons for missing data across groups Missing data was used appropriate methods. For continuous outcome data, difference in mean or standard deviation among missing outcomes was not clinically sufficient relevant bias in observed effect size.	Reasons for missing outcome data were related to true outcome with either imbalance numbers or reasons for missing data across intervention groups Missing data was used inappropriate methods. For continuous outcome data, difference in mean or standard deviation among missing outcomes was clinically sufficient relevant bias in observed effect size.	Insufficient detail in reporting attrition rate to judge either yes or no No description of number of randomisation, reasons of missing data or outcomes
Selective outcome reporting: Judging for		
The study protocol was available. Primary and secondary outcomes were interested and reported in the pre-specified way. If the study protocol was not available but clear to publish studies that included all expected outcomes, those were pre-specified.	None of all primary outcomes were reported. One or more primary outcomes were reported using measurements, and analysis methods or subsets of the data were not pre-specified. One or more reported primary outcomes were not pre-specified e.g. an unexpected adverse effect. The study report excluded results for a key outcome that would be expected to report in the study.	Insufficient detail to judge either yes or no
Other bias: Judging for		
Appeared to be free of other sources of bias	Either one of: Had a potential source of bias related to the specific study design Stopped early due to some data-dependent process Had extreme baseline imbalance Claimed to be fraudulent Had some other problems	Insufficient detail to assess whether or not an important risk of bias exists Insufficient rationale or evidence to identify problems that introduced bias

Table A4.2 Form for rechecking risk of bias by a second reviewer

Bias	Author's judgement		
	Low risk	Unclear risk	High risk
Random sequence generation (selection bias)	☐	☐	☐
Allocation concealment (selection bias)	☐	☐	☐
Blinding of participants and personnel (performance bias)	☐	☐	☐
Blinding of outcome assessment (detection bias)	☐	☐	☐
Incomplete outcome data (attrition bias)	☐	☐	☐
Selective reporting (reporting bias)	☐	☐	☐
Other bias	☐	☐	☐

Appendix 5 Data from included studies

Studies are listed alphabetically.

Anderson 2011[144]

Article identification: 1/2011	Reviewer's initials: SS	Verifier's initials: HB
Author and year: Anderson 2011		Country: US
Objectives	Compared effects of a standardised behavioural intervention using meal replacements (MRs), fruits and vegetables (MR-FV) and increased physical activity with a usual-care intervention on body weight change	
Methods		
Participants	Inclusion criteria: Subjects aged 20-65 years with BMI between 30 and 39.9 kg/m^2 and being good health.	
	Exclusion criteria: Pregnant, unable to read and write in English, allergy to MRs ingredients, participated in other clinical studies, lost or gained > 5 lb during the previous 3 months, used weight-loss medications or supplements and anticoagulants or oxcarbazepine, diagnosed as diabetes mellitus or had a fasting plasma glucose value ≥ 126 mg/dL	
	Settings and/or locations: University medical centre	
	Duration: 24 weeks	
	Recruitment methods: The study advertised by newspapers, radio, bulletin board announcements or word of mouth. Interested subjects were screened by telephone asking questions by the study coordinator. The orientation was described by the senior author and study coordinator. The screening visit and randomisation were performed by a study physician.	
	Sample size: 45 participants randomised	
Study design	Randomisation-sequence generation: Randomised controlled trial used random numbers in blocks of 10 subjects. 5 of every 10 subjects were selected to each group.	
	Allocation concealment: 23 participants were randomly assigned to MR-FV group. 22 participants were randomly assigned to the control group. No further report	
	Implementation: 2 lead physicians (2 investigators) randomly assigned participants to 2 study groups.	
	Blinding: Blinded 2 lead physicians (2 investigators)	
	Statistical methods: The primary outcome was presented by the percentage weight change from baseline to 24 weeks in the trial. 80% power was used for sample size calculation. Participants were analysed as completers, available cases and ITT. Baseline values used mean ± SD whilst follow-up values used mean ± SE. Comparison between groups used 2-sample independent t tests with 2-sided significance at $p \leq 0.05$. Data analysis used SAS V9.1.	

Anderson 2011 (continued)

Methods	
Intervention	Healthy solutions option: Meal replacements, fruits and vegetables (MR-FV) provided a low-energy diet as details below. Participants: - Attended weekly weight-loss classes for 16 weeks and weekly maintenance classes for 8 weeks - 90-minute "core" weight-loss classes for the first 12 weeks - 90-minute "ongoing" weight-loss classes for 4 weeks - 60-minute "maintenance" classes for the remaining 8 weeks - Consumed 3 HMR shakes, 2 HMR entrées and 5 servings of fruits or vegetable daily - Were given a weekly progress chart, kept record the numbers of MRs; fruits and vegetables consumed daily and recorded the calories burned in exercise Weight maintenance classes: - Consumed 2 MRs daily and continued 5 servings of fruits and vegetables daily - Kept record daily all MR and food intake - Achieved exercise goals (expand ≥ 8.4 mJ/week or 2000 kcal) - Made midweek phone calls to report their nutrition intake and physical activity
Comparison/ Control	Usual-care weight-loss counselling from an experienced or a registered dietician Participants counselled at baseline, 8 weeks and 16 weeks about: - At the initial session, participants discussed about their weight loss target and any current health conditions related to obesity. - Next, counselled with a dietician about how to maintain a nutritionally balanced, energy-restricted diet that provided 30% of energy from fat, 50% from carbohydrate and 20% from protein - Received multivitamin tablets to take one daily
Outcomes	Primary outcome measures: Weight change at 24 weeks Secondary outcome measures: Side effects, behavioural patterns and risk factors at 8 and 16 weeks
Results	
Participant flow	48 individuals screened. 3 persons failed screening. 45 participants randomised. 23 participants were randomly assigned to MR-FV group. 22 participants were randomly assigned to the control group. ITT: 38 enrolled to the treatment (22) and control (16) group.
Baseline data	Table 1: Baseline characteristics of participants, mean (± SD)

	Control group, n = 16	MR-FV group, n = 22
Female, n (%)	12 (75.0)	17 (77.3)
Age, years	45.4 (10.2)	50.5 (7.3)
Weight, kg [mean (± SE)]	99.2 (3.3)	99.7 (3.2)
BMI, kg/m^2	34.9 (2.7)	35.8 (3.2)

	Participants' characteristics in both groups were similar. However, there were 76% of female with mean aged 48 years and had mean BMI 35 kg/m^2 and mean weight 99 kg, approximately.
Number analyzed	ITT: 22 participants in the intervention group, 16 participants in the control group Completers: 31 participants completed the last observation carried forward. 18 participants in the intervention group, 13 participants in the control group

Anderson 2011 (continued)

Results					
Outcomes and estimation					
Table 2: Changes in weight from baseline, mean (± SE)					
	Control group		MR-FV[a] group		*p*-value[b]
	ITT [a], n = 16	Completers, n = 13	ITT[a], n = 22	Completers, n = 18	
Weight change, %					
8 weeks	-1.3 (0.9)	-1.4 (0.7)	-8.5 (0.6)	-8.9 (0.6)	<0.0001
16 weeks	-0.7 (1.1)	-0.7 (1.1)	-12.5 (0.9)	-13.8 (0.7)	<0.0001
24 weeks	-0.7 (1.1)	-0.6 (1.2)	-13.9 (1.1)	-15.4 (1.0)	<0.0001
[a]MR-FV = meal replacement, fruit and vegetables, [b]*p*-value < 0.05 considered statistically significant					
At 24 weeks for ITT analysis, obese participants' mean weight loss in MR-FV group (13.9 kg, 13.9%) was greater than those in the control group (0.7 kg, 0.7%) as well as completers analysis, their mean weight loss in MR-FV group (15.4 kg, 15.4%) was greater than those in the control group (0.7 kg, 0.7%). As a result, obese participants' weight decreased over 10% of the initial weight, 13.9% in ITT and 15.4% in completer analysis. There were statistically significant differences between groups for both ITT and completer analysis ($p < 0.0001$).					
Secondary outcome	At 16-week weight loss period, WC ($p < 0.01$), glucose ($p = 0.02$) and LDL-C ($p < 0.05$) were significantly greater decrease in MR-FV group. Adherence was self-reported record and found that there was good (85%-90%) to excellent (> 95%) in participants' adherence. Results also presented weight maintenance and behavioural assessments but not extracted here. Only adherence was presented.				
Adverse events	Participants' adverse effects were higher than 50% in both groups. Participants in C group (56.3%) were less adverse events than those in MR-FV group (59.1%).				
Discussions					
Interpretation	Introduction - Reviewed the prevalence of overweight in the globe and also in the US - Reviewed the relevant studies about the effect of commercial weight loss programmes - Described the matter of this study: Limited studies of RCTs for commercial weight loss programme used meal replacement products in the community pharmacy - Focused on a behavioural/nutritional intervention programme by physician counselling expenditure of obesity affected costs in the US - Explained the primary and secondary objectives				
	Methods Randomised controlled trial: Randomisation-sequence was generated by blocking of 10 subjects and selected 5 of every 10 subjects to each group. Numbers of subjects were reported as allocation concealment and shown numbers excluded and completed as the participant flow. Implementing randomisation and blinding by 2 lead physicians (investigators) Comparison of 2 treatment groups: MR-FV group provided a low-energy diet with weight loss products whilst control group with usual-care weight-loss counselling from an experienced or a registered dietician. At baseline, no statistically significant differences. Provider: Physician, a registered dietician Assessing outcomes: Measured weight in triplicate on an electronic scale (Detecto, Model 6800, Webb City, MO) with subjects wearing the light cloth without shoes. This should be valid in terms of measuring weight.				

Anderson 2011 (continued)

Discussions	
Interpretation (continued)	Statistical methods: Reported power calculation, value presented, tests used, *p*-value and programme used. Power calculation was 80% to detect a 4.5% difference in mean weight loss between groups and complete at least 16 subjects each group by assuming a SD of 5% and 1-tailed of significance at the 0.05 level. Power calculation could help this study for: 1) Scanning whether or not participants randomised were enough to see an effect and 2) preparing for sufficient participants if they declined to participate during the study. At 24 weeks of weight loss period, values presented only the available cases.
	Results - Participant flow presented including number of screening, randomisation, exclusion, allocation, and ITT and completers analysis - Reported values as mean weight with SD or SE - Both diets reported statistically significant differences using 2-sample independent t-tests ($p < 0.05$). - MR-FV group was presented weight loss at 24 weeks with ITT and completers analysis. However, the primary data analysis was ITT so that the percentage of obese participants' weight loss decreased about 13.9% of their initial weight.
	Discussion The authors discussed about the mildly or moderately obese people who participated in the MR-FV programme (12.5% of the initial weight, ITT and 13.8% completers) were similarly effective weight loss to other studies, particularly Medifast (12.3% at 16 weeks, completers). Unlikely, other commercial weight loss programme evidences such as Weight Watchers, Jenny Craig, Medifast, Nurtisystem,etc. were hardly compared outcomes because of difference in comparator trials such as type and duration of programme. The authors also referred to commercial weight loss programmes with food choices affected greater weight loss as well as commercial programmes combination with the behavioural modification. Therefore, subjects who participated in HMR programme could have over 10% weight loss of their initial weight at 16 weeks.
Generalisability	Did not report
Other evidence	General comments This study compared to other weight loss programmes claimed that it was impossible to be the most effective commercial weight loss programmes. No comments on genralisability and factors related weight loss were risk factors, adverse events and behavioural adherence. Also, limitations were conducting at a single site and a small number of subjects. The control group subjects were having fewer visits and interactions with clinical staff. Regarding small sample size, the impact of MR use, fruit and vegetable consumption and exercise on weight loss have not been evaluated. For further research, the study will be needed to examine the comparative effectiveness of the 3 major components: MR use, fruit and vegetable consumption, and exercise and can be effectively provided by physicians.
Funding	-

Dansinger 2005[11]

Article identification: 1/2005	Reviewer's initials: SS	Verifier's initials: HB
Author and year: Dansinger 2005		Country: US

Objectives	Determined the effectiveness of 4 popular diets (Atkins, Zone, Weight Watchers and Ornish) on weight loss and cardiac risk factor reduction
Methods	
Participants	Inclusion criteria: Overweight or obese participants - Aged 22-72 years with BMI 27-42 kg/m^2 - Had at least 1 of the metabolic cardia risk factors: Hypertension (SBP/DBP ≥ 145/90 mmHg), fasting hyperglycemia (BG ≥ 110 mg/dL or ≥ 6.1 mmol/L), dyslipidemia (TC ≥ 200 mg/dL or ≥ 5.2 mmol/L), LDL cholesterol (≥ 130 mg/dL or ≥ 3.4 mmol/L), HDL cholesterol (≤ 40 mg/dL or ≤ 1.0 mmol/L), triglycerides (≥ 150 mg/dL or ≥ 1.7 mmol/L) - Used oral medications to treat hypertension, diabetes or dyslipidemia
	Exclusion criteria: Overweight or obese participants had - Unstable chronic illness, insulin therapy, urinary microalbumin > 2 times normal, serum creatinine ≥ 1.4 mg/dL (≥ 123.8 μmol/L) - Clinically significant abnormalities of liver or thyroid test results, weight loss medication, pregnancy
	Settings and/or locations: Academic medical centre in Boston, Massachusetts
	Duration: 1 year
	Recruitment methods : Recruited participants via newspaper advertisements and television publicity (local news) in the Greater Boston area Race and sex criteria were designed for the recruitment strategy.
	Sample size: 160 participants randomised
Study design	Randomisation-sequence generation: A single-centre randomised trial A computer generated the randomised Latin-square sequence 10 participants were assigned to 1 of 4 class rosters. Each diet was conducted to each of the class times only once in order to minimise the potential confounding between class time and diet type. A new set of diet classes was run every 3-4 months for 4 cycles. 40 participants each in Atkins, Zone, Weight Watchers (WW) and Ornish
	Allocation concealment: No description
	Implementation: Dietician and physician
	Blinding: Participants were blinded by the study statistician. Study nurses and laboratory personnel who evaluated outcomes were blinded.
	Statistical methods: Sample size calculation used 80% power. Using t tests was to compare the mean absolute change from baseline to 1 year. Using ANOVA was to evaluate differences of baseline variables among diet groups, and independent t tests were used to compare baseline variables among participants. Absolute changes at 2, 6 and 12 months were normal distribution for weight loss and used 1-sample t test whilst non-normal distribution used Wilcoxon rank sum test.

Dansinger 2005 (continued)

Methods	
Study design	Data analysis used SPSS V10.1 with 2-sided significant at $p \leq 0.05$.
All interventions	All participants received supplements (non-prescription multivitamin daily), exercise (at least 1 hour per week) and external support (commercial support services).
Intervention 1	Atkins diet (Carbohydrate restriction): Carbohydrate daily < 20 g with gradual increase up to 50 g per day
Intervention 2	Zone diet (Macronutrient balance): 40-30-30 balance of carbohydrate, fat and protein in percentage calories
Intervention 3	Weight Watchers diet (Calorie restriction): Keep total daily points in a range of current weight. Each point was 50 calories. Most participants intended 24-32 points per day.
Intervention 4	Ornish diet (Fat restriction): A vegetarian diet contained 10% of fat calorie
Outcomes	Primary outcome measures: Weight loss at baseline, 2, 6 and 12 months Other outcome measures: 1) Cardiac risk factors: Waist size, BP, serum total cholesterol, HDL-C, triglycerides, glucose, insulin, high density C-reactive protein and creatinine levels, and 2) self-selected dietary adherence rates per self-report
Results	
Participant flow	1010 overweight or obese adults telephone inquiries. 763 adults excluded. 247 participants screened individually. 87 participants excluded. 160 participants randomised. 40 participants each assigned to Atkins, Zone, Weight Watchers and Ornish
Baseline data	

Table 1: Participants' characteristics at baseline, n = 40 each, mean (± SD)

	Atkins	Zone	WW	Ornish	All diets, n = 160
Age, year	47 (12)	51 (9)	49 (10)	49 (12)	49 (11)
Women, n (%)	21 (53)	20 (50)	23 (58)	17 (43)	81 (51)
Weight, kg	100 (14)	99 (18)	97 (14)	103 (15)	100 (15)
BMI, kg/m^2	35 (3.5)	34 (4.5)	35 (3.8)	35 (3.9)	35 (3.9)

Notes: There were no significant differences in all diet groups because of *p*-value > 0.05.

Participants' characteristics were not significant differences among all diet groups. There were 51% of women with mean aged 49 years and had mean BMI 35 kg/m^2 and mean weight 100 kg, approximately.

Number analyzed	ITT: 40 participants each assigned to Atkins, Zone, Weight Watchers and Ornish Completers: 21 participants in Atkins, 26 participants in Zone, 26 participants in Weight Watchers and 20 participants in Ornish

Dansinger 2005 (continued)

Outcomes and estimation

Table 2: Weight change from baseline to 2, 6 and 12 months in analysis with baseline values carried forward in the case of missing data[*], n = 40 each, mean (± SD)

	Atkins	Zone	WW	Ornish	*p*-value across diets
Weight, kg					
2 months	-3.6 (3.3)[**]	-3.8 (3.6)[**]	-3.5 (3.8)[**]	-3.6 (3.4)[**]	0.89
6 months	-3.2 (4.9)[**]	-3.4 (5.7)[**]	-3.5 (5.6)[**]	-3.6 (6.7)[**]	0.76
12 months	-2.1 (4.8)[**]	-3.2 (6.0)[**]	-3.0 (4.9)[**]	-3.3 (7.3)[**]	0.40
BMI, kg/m^2					
2 months	-1.3 (1.1)[**]	-1.3 (1.2)[**]	-1.2 (1.3)[**]	-1.2 (1.1)[**]	0.83
6 months	-1.1 (1.7)[**]	-0.9 (2.4)[**]	-1.2 (2.0)[**]	-1.2 (2.3)[**]	0.65
12 months	-0.7 (1.6)[**]	-1.1 (2.0)[**]	-1.1 (1.7)[**]	-1.4 (2.5)[***]	0.36

[*]Atkins participants: 31 at 2 months (mo), 22 at 6 mo and 21 at 12 mo, Zone participants: 33 at 2 mo, 26 at 6 mo and 26 at 12 mo, Weight Watchers participants: 33at 2 mo, 30 at 6 mo and 26 at 12 mo, Ornish participants: 29 at 2 mo, 21 at 6 mo and 20 at 12 mo. [**]Significant at $p < 0.01$ for difference from baseline within groups

[***] Significant at $p < 0.05$ for difference from baseline within groups

At 1 year, overweight or obese participants' mean weight loss in Atkins diet (2.1 kg, 2.1%), Zone diet (3.2 kg, 3.2%), Weight Watchers diet (3.0 kg, 3.0%), Ornish diet (3.3 kg, 3.2%) were statistically significant difference within groups ($p < 0.01$). However, there was no statistically significant difference between groups ($p = 0.40$).

Table 3: Weight change from baseline to 2, 6 and 12 mos in analysis with missing data excluded[a], mean (± SD)

	Atkins	Zone	WW	Ornish	*p*-value[b] within grs
Weight, kg					
2 months	-4.7 (2.9)	-4.6 (3.4)	-4.2 (3.8)	-5.0 (3.0)	< 0.01
6 months	-5.8 (5.3)	-5.2 (6.4)	-4.7 (6.1)	-6.7 (8.0)	< 0.01
12 months	-3.9 (6.0)	-4.9 (6.9)	-4.6 (5.4)	-6.6 (9.3)	< 0.01
BMI, kg/m^2					
2 months	-1.6 (1.0)	-1.6 (1.2)	-1.5 (1.3)	-1.7 (1.0)	< 0.01
6 months	-2.0 (1.9)	-1.7 (2.2)	-1.7 (2.1)	-2.4 (2.7)	< 0.01
12 months	-1.4 (2.1)	-1.6 (2.3)	-1.7 (1.9)	-2.3 (3.2)	< 0.01

[a]Atkins participants: 31 at 2 months (mo), 22 at 6 mo and 21 at 12 mo, Zone participants: 33 at 2 mo, 26 at 6 mo and 26 at 12 mo, Weight Watchers participants: 33at 2 mo, 30 at 6 mo and 26 at 12 mo, Ornish participants: 29 at 2 mo, 21 at 6 mo and 20 at 12 mo. [b]Significant at $p < 0.01$ for difference from baseline within groups

Dansinger 2005 (continued)

Results	
Secondary outcome	At 1 year, LDL/HDL-C ratio was significant reduction approximately 10% (all $p < 0.05$) whereas SBP, DBP and glucose were not significant difference. Results also presented dietary adherence and changes in exercise but not extracted here.
Outcomes and estimation	At 1 year with missing data excluded, overweight or obese participants' mean weight loss in Atkins diet (3.9 kg, 3.9%), Zone diet (4.9 kg, 4.9%), Weight Watchers diet (4.6 kg, 4.6%), Ornish diet (6.6 kg, 6.4%) were statistically significant difference within groups ($p < 0.01$).
Adverse events	Not be able to identify diet related adverse effects
Discussions	
Interpretation	Introduction - Reviewed the widespread of obesity that made more patients and clinicians were interested in using popular diets for weight loss - Reviewed the 4 popular diets that were Atkins, Ornish, WW and Zone diets about the diet differences - Described the matter of this study: Limited studies regarding the relative benefits, risks, effectiveness and sustainability of popular diets - Explained aim of this study
	Methods A single-centre randomised trial: A computer generated the randomised Latin-square sequence. Overweight or obese participants were allocated to 1 of 4 class rosters. Dietician and statistician implemented randomisation. There was double blind because participants, study statistician, study nurses and laboratory personnel were blinded. Comparison of 4 diets: Atkins diet (Carbohydrate restriction), Zone diet (Macronutrient balance), Weight Watchers diet (Calorie restriction) and Ornish diet (Fat restriction) were different restriction of calorie. At baseline, no statistically significant differences. Provider: Dietician, physician Assessing measures: Measured weight by using a single calibrated scale (Detecto, Webb City, MO) of participants wearing light clothing and no shoes. Although there was no report of measuring height, weight values should be valid. Statistical methods: Reported power calculation (80%) to detect a weight change of 2% from baseline and 3% between diets. Power calculation could help this study for: 1) Scanning whether or not participants randomised were enough to see an effect, 2) not wasting time on an underpowered study and 3) preparing for sufficient participants if they declined to participate during the study. Reported analysis of baseline carried forward with and without missing data and completers (greater results), *p*-value, tests used and programme analysed, however, confidence intervals were unavailable.
	Results - Reported participant flow, numbers excluded and analysed by ITT or completers and reasons of declining for follow-up - Reported values in mean weight with SD - All 4 diets reported statistically significant differences ($p \leq 0.05$). - At 1 year for completers, all diets could significantly decrease participants' weight loss.

Dansinger 2005 (continued)

Discussions	
Interpretation (continued)	Discussion This study was reported that a variety of popular diets could reduce weight, however, there was the minority of participants who were highly dietary adherence. Although there was high adherence level, there was not with diet type. Nevertheless, at 1 year of weight loss, the highest reduction was Ornish. Regarding to weight loss, the higher overweight or obese adults related to cardiac risks, the more increase dietary adherence rates needed. The authors' recommendation to improve adherence was matching individuals with their food preferences, lifestyles and cardiovascular profiles. However, this study was double blind so that participants could not select their diet programmes. It would affect adherence. Moreover, this study supported carbohydrate and saturated fat restriction because this could be effective to cardiovascular disease. Three types of diets were discussed: 1. Low carbohydrate increased HDL but decreased TG, glucose, the key predictor of weight loss and cardiac risk factors reduction. 2. Similarly, low carbohydrate/high-fat diets increased HDL, however, it was insufficient evidence of the relevant dietary intervention trials. 3. Likewise, high saturated fat increased HDL but decreased LDL/HDL-C that would not benefit to lipid profiles. Reasonably, it could be demonstrated that any diet type decrease weight and cardiac risk factors but was not potentially recommended because either carbohydrate or fat restriction depended on individual profiles as lifestyle, health and medical conditions and food preferences.
Generalisability	Applicable because discontinuous participants were similar to other groups, had higher evidence of weight loss than weight gain and attained the meaningful weight loss
Other evidence	General comments There were several limitations which were 1) Lack of a long-term support system (low adherence), 2) Each diet was not identified as a best diet (popular diets), 3) A larger sample size may be required and 4) Adverse effects were not reported. Further study: Needed to study the cardiovascular and other health effects of dietary alternatives
Funding	The General Research Centre via the National Centre for Research Resources of the National Institutes of Health (NIH)

Djuric 2002[145]

Article identification: 1/2002	Reviewer's initials: SS	Verifier's initials: HB
Author and year: Djuric 2002		Country: US
Objectives	Investigated the effects of combining weight-loss counselling with the Weight Watchers plan on weight loss for obese women with breast cancer	
Methods		
Participants	Inclusion criteria: Women aged 18-70 years, breast cancer stage 1 and 2 with diagnosed within 4 years, completed chemotherapy or radiation therapy at least 3 months	
	Exclusion criteria: Did not report	
	Settings and/or locations: Single-centre	
	Duration: 12 months	
	Recruitment methods: Recruited by mailing to participants of "Race for the Cure", press releases and brochures at breast clinics	
	Sample size: 48 participants randomised.	
Study design	Randomisation-sequence generation: Randomised pilot study (Prospective trial) 48 participants randomised and assigned to 1 of 4 groups: Control, Weight Watchers (WW), individualised counselling or a combination of WW and individualised counselling No further description	
	Allocation concealment: No description	
	Implementation: Did not report	
	Blinding: Did not report	
	Statistical methods: Means of each group were compared by paired or Student's t test or ANOVA with a Scheffe post hoc test for significance between groups. $\chi 2$ tests were used to compare the proportions. Data analysis used SPSS V10.1 with significant at $p \leq 0.05$.	
Intervention 1	Weight Watchers arm: Attended weekly WW meeting without dietary or exercise instruction	
Intervention 2	Individualised arm: Dietician scheduled weekly for the first 3 months, biweekly at month 3 to 6 and monthly thereafter. Contacted by telephone One-on-one counselling provided diet and exercise by a registered dietician. Weight loss goal: 10% decreased out of the initial baseline weight over 6 months The dietary goal: Used the American Dietetic Association Exchange List diet plan Energy intake: Decreased 500 to 1000 kcal/d. Target fat intake: 20% to 25% of energy from fat. Fruit and vegetable intake: At least 5 serving/d. Protein intake: Up to 20% of energy. Counselling approach used the theoretical framework of Bandura's social cognitive theory. Subjects encouraged addressing their thoughts and beliefs about themselves and their weight, regarding self-image and self-acceptance.	
Intervention 3	Comprehensive arm: Received the individualised counselling and attended weekly WW. Omitted monthly meeting because of adding the dietician-led monthly group. The weekly WW programme has dietary and cancer-prevention guidelines plus details of the dietary-exchange goals. Participants could assign for their personal diet plan by learning the points system of WW, which takes into account energy; fat and fibres contents of foods including the food-group exchanges. Also requested to daily keep exercise and dietary logs.	

Djuric 2002 (continued)

Methods	
Comparison/ Control	Control arm: Subjects received the national Cancer Institute's "Action Guide to Healthy Eating" and the "Food Guide Pyramid" pamphlets. No other dietary or exercise instructions or help Met dietician at baseline, 3, 6 and 12 months
Outcomes	Primary outcome measures: Mean weight loss at 3, 6 and 12 months
Results	
Participant flow	48 participants randomised. 9 excluded. At 12 months, 39 participants remained. 12 participants in control, 8 participants in WW, 9 participants in individualised counselling and 10 participants in combination of WW and individualised counselling
Baseline data	Participants' demographics: Obese women' age ranged from 36 to 70 years with weight 95.4 kg and BMI 35.5 kg/m^2 at the study entry.
Number analyzed	ITT: 12 participants each in control, WW, individualised counselling, and combination of WW and individualised counselling Completers at 12 months: 12 participants in control, 8 participants in WW, 9 participants in individualised counselling and 10 participants in combination of WW and individualised counselling
Outcomes and estimation	At 12 months, mean weight loss was 0.85 ± 6.0 kg in control group, -2.6 ± 5.9 kg in WW and -8.0 ± 5.5 kg in the individualised group. Obese participants in comprehensive groups were higher weight loss than other groups at 3 (7.4 kg), 6 (9.3 kg) and 12 (9.4 ± 8.6 kg) months whilst those in control, WW and individualised counselling groups approximately lost weight range from 1 kg to 4 kg at 3 months and range from 1 kg to 8 kg at 6 and 12 months, respectively. As a consequence, there was statistically significant difference from control group at 3, 6 and 12 months ($p < 0.05$).
Other outcomes	Other results also presented group attendance, telephone counselling, dietary intake and exercise but not extracted here.
Adverse events	Did not report
Discussions	
Interpretation	Introduction - Reviewed the weight loss methods in the previous studies and factors related to obesity such as survivors from breast cancer, group counselling approach and demographic characteristics e.g. race, health risk factors. - Described the matter of this study: No studies used individualised counselling methods combination with weight loss programme - Explained the aim of this study
	Methods Randomised pilot study (Prospective trial): Randomisation-sequence generated and assigned 48 participants to 1 of 4 groups: Control, Weight Watchers (WW), individualised counselling or a combination of WW and individualised counselling. Implementation and blinding were not applicable. The reasons were that investigators and participants need to know what weight loss structures are and how to advise in details for each arm. This would affect to how participants complied to weight loss programme as well. Comparison of 4 arms: control, Control, WW, individualised counselling and comprehensive arms Assessing outcomes: Measured weight in clothing with no shoes using a professional beam scale (model 402KLS, Health-o-Meter, IL). Although there was not informed height measurement, weight values could be acceptable. Provider: A registered dietician

Djuric 2002 (continued)

Discussions	
Interpretation (continued)	Methods (continued) Statistical methods: Reported *p*-value, tests used and programme analysis, however, no report of power calculation and confidence intervals. Therefore, this study may not be enough participants randomised to see an effect and insufficient participants if they declined to participate during the study.
	Results - No report of participant flow but explained in details of numbers excluded, remained for ITT and completers analysis - Reported values in mean weight with SD and also presented as a graph - All diets reported statistically significant differences at $p \leq 0.05$. At baseline, results of participants' characteristics presented as a whole sample size because of a small number of each group. - Obese participants in comprehensive groups were highest weight loss than other groups at 3 (7.4 kg), 6 (9.3 kg) and 12 (9.4 kg) months and statistically significant difference from control group at 3, 6 and 12 months ($p < 0.05$).
	Discussion The authors discussed about the major target of interventions with breast cancer survivors and what factors related to participants. This study gave examples of factors related such as exercise, dietary changes and quality and weight loss approaches e.g. group support, individuals. Based on other evidences, comparing to the counselling methods, this study found that the individualised and comprehensive arms were similar to the behavioural modification used in the Lifestyle, Exercise, Attitudes, Relationships and Nutrition (LEARN) programme. Moreover, weight loss counselling in this study was individual contacts by telephone to increase fruit and vegetable consumption and decrease fat intake in participants. It was suggested that participants were successful weight loss by using this counselling method. Compared with e-mails contact, this method also showed the effective weight loss, however, it is only any participant who can access the Internet. Thus, telephone contact was more convenient in the similar success of weight loss.
Generalisability	Did not report
Other evidence	General comments This study concluded that the comprehensive arm was the most successful weight loss. It was not only integrated between WW and individualised counselling but also consisted of diet, exercise, social support. Therefore, one approach with the combination of individualised counselling and the commercial WW programme was the most effective weight loss. Further study: The comprehensive arm with the combination of individualised counselling and the commercial WW programme should be applicable in the larger studies and also useful in people who suffered from other medical complications of obesity.
Funding	NIH, The Weight Watchers Group, Inc. and The Ford Motor Company Fund

Donnelly 2007[146]

Article identification: 1/2007	Reviewer's initials: SS	Verifier's initials: HB
Author and year: Donnelly 2007		Country: US

Objectives	Compared the efficacy between a phone and a traditional face-to-face clinic approach to achieve 10% weight loss and weight maintenance
Methods	
Participants	Inclusion criteria: Men and women participants aged 25-68 years with BMI 33.2 ± 3.8 kg/m^2, were healthy from a written medical history, stable weight and BP medications.
	Exclusion criteria: Participants used tobacco products, had metabolic disease and medications after metabolism.
	Settings and/or locations: Weight management clinic
	Duration: 12 weeks
	Recruitment methods: A detailed letter
	Sample size: 96 participants (24 men, 72 women)
Study design	Randomisation-sequence generation: No description. Randomised controlled trial
	Allocation concealment: Did not report
	Implementation: Did not report
	Blinding: Did not report
	Statistical methods: Used Kruskal-Wallis test to compare all 3 groups at 12 weeks (weight-loss duration). Weight and BMI were summarised in median (range).
Intervention 1	Phone group: Weight management clinic weekly - Conducted 60 minutes - Participated via a group conference call with health educators - Received the behaviourally based clinic on lifestyle change, physical activity and nutrition and MR by post - Self-reported on weight
Intervention 2	Clinic group: Weight management clinic weekly - Conducted 60 minutes - Attended a traditional face-to-face clinic with health educators - Received the behaviourally based clinic on lifestyle change, physical activity and nutrition and MR at the clinic site - Reported their weight on a scale at the clinic site
Intervention 1 and 2	Weight loss diet: Total calories for the day are 1250 kcal comprised of 5 MR (3 shakes, 2 entrees), 7 total fruits and vegetables.
	Physical activity: Targeted at least 2000 kcal/week by using a progressive protocol of both structured exercise and lifestyle PA The first 4 weeks: Started with a daily 15-min session and add about 10 more minute/day each week for the next 3 weeks
Control	Did not report details of the programme

Donnelly 2007 (continued)

Methods	
Outcomes	Primary outcome measures: Weight loss and weight maintenance but not extracted here including secondary outcome measures such as attendance, meal replacements (MRs), fruits/vegetables (F/V) and physical activity (PA).
Results	
Participant flow	Did not report

Baseline data

Table 1: Participants' characteristics at baseline, median (range)

	Phone, n = 25	Clinic, n = 27	Control, n = 22
Age, years	53 (42)	52 (29)	46 (29)*
Male/Female	9/16	10/17	4/18
Weight, kg	102.5 (51.2)	95.6 (66.6)	88.2 (54.9)
BMI, kg/m^2	34.6 (14.8)	32.8 (14.3)	31.5 (12.6)

*Significantly different from phone and clinic groups at $p < 0.05$

Participants' characteristics in all 3 groups were similar in terms of majority of women with aged 50 years, and mean weight 95 kg and BMI 33 kg/m^2, approximately.

Number analyzed	ITT: 25 participants in phone group, 27 participants in clinic group and 22 participants in control group

Outcomes and estimation

Table 2: Weight change in median and percentage at 12 weeks

	Phone, n = 25	Clinic, n = 27	Control, n = 22
Weight, kg			
Baseline	102.5 (51.2)	95.6 (66.6)	88.2 (54.9)
Week 12	10.6 (16.6)*	12.7 (19.9)*, a	0.25 (5.6)
Weight , %			
< 10	10	6	-
10-14.9	10	10	-
15-19.9	5	11	-
≥ 20	-	-	-

*Significantly different from control groups at $p < 0.05$

[a]Significantly different between phone and clinic groups at $p < 0.05$

At 12 weeks, the median of clinic group was the greatest weight loss with 82.9 kg (13.7%, n = 21) whilst the phone group lost weight of 91.9 kg (10.4%, n = 15), and control group lost 88.0 kg (0.2%). Both phone and clinic approaches were statistically significant difference when compared with control group.

Adverse events	Did not report
Discussions	
Interpretation	Introduction - Defined obesity and the association such as life expectancy and health risk factors. However, there was not shown the percentage of US adults who were obese. The article reported roughly in terms of ratio of obese people and US population.

Donnelly 2007 (continued)

Discussions	
Interpretation (continued)	Introduction (continued) - Reviewed reasons of not researching Internet but interested in phone approach and also the advantages of phone approach in the weight loss programme. - Described the matter of this study: The previous research studied telephone counselling compared with a mail intervention or standard care for 6 months. However, this study was doing the phone intervention compared with clinic counselling for 3 months. Did not report that no studies have been done before; however, explained the aim and primary outcome of this study
	Methods Randomised controlled trial. Allocation concealment, implementation and blinding were not applicable. Comparison of 3 weight loss deliveries: Phone vs clinic approach and control group. No report of what control group looked like. Sample of weight loss diet was shown in a list of breakfast, mid-morning snack, lunch, afternoon snack, dinner and late-night snack. At baseline, there were only statistically significant differences in participants' ages. Assessing outcomes: Measured weight in a standard hospital gown by a calibrated digital scale, ± 0.1 kg accurately. Weight values should be valid even though there was not informed height measurement. Provider: Physician, health educator Statistical methods: Reported only tests used to compare all 3 groups at the particular time point, however, power calculation, significant level, programme used and confidence intervals were unavailable. Data analysis used nonparametric test to compare weight change of sample size in each group and presented values as median (range) from SPSS. This study has no power calculation so that it may not be enough participants randomised to see an effect and insufficient participants if they declined to participate during the study.
	Results - No report of participant flow but reported values in median weight with range - All approach groups reported statistically significant differences ($p < 0.05$). - At 12 weeks, weight loss in the clinic and phone groups was statistically significant difference from baseline whilst both phone and clinic approaches were statistically significant difference when compared with control group.
	Discussion The authors firstly discussed about the study type, intervention groups and primary outcomes of this study. Weight loss at 12 weeks was presented in median and shown that there was significantly different between phone and clinic approaches. Moreover, weight loss achieved over 10% weight loss from baseline. This met the National Heart, Lung, and Blood Institute (NHLBI) guidelines. The reason of 10% weight loss of the initial weight was that the recommendation of NHLBI in order to improve chronic disease. Secondly, comparing to other previous studies, findings were not different from those at the similar approach. Lastly, limitations were mainly female, and self-reported could be under or over estimation (e.g. height).
Generalisability	Did not report
Other evidence	General comments Comparison between a phone approach and the traditional weight management clinic was similar success at 10% weight loss of the initial weight at baseline. Further study: Focused on cost analysis
Funding	Health Management Resources

Foster 2009[147]

Article identification: 1/2009	Reviewer's initials: SS	Verifier's initials: HB
Author and year: Foster 2009		Country: US
Objectives	Assessed the effects of a commercially available weight loss programme on weight and glycemic control among obese patients with type 2 diabetes	
Methods		
Participants	Inclusion criteria: Obese patients with type 2 diabetes with BMI 30-50 kg/m^2, aged 21-75 years, screened $HbA_{1c} \geq 6$, allowed to use Metformin; Thiazolidinediones; Sulfonylureas	
	Exclusion criteria: Obese patients had serious medical illness such as uncontrolled hypertension (≥ 180/100 mmHg), took lipid-lowering medications or medications affected body weight, pregnant or lactating and used diabetes treatment e.g. insulin.	
	Settings and/or locations: Temple University	
	Duration: 3 months for weight loss	
	Recruitment methods: Recruited via newspaper advertisements, flyers and physician referrals from August 2007 to December 2008	
	Sample size: 69 patients randomised	
Study design	Randomisation-sequence generation: Randomised study. Used random-number generator to a prepackaged, portion-controlled diet plan (PCD) or a diabetes support and education (DSE) programme	
	Allocation concealment: Insufficient information	
	Implementation: Statistician generated the randomisation sequence and allocation concealment. The research coordinator enrolled participants and randomly assigned them to either group.	
	Blinding: Did not report	
	Statistical methods: Differences between groups at baseline used independent samples t tests or Wilcoxon rank-sum tests for continuous variables and χ^2 for categorical variables. ITT analysis used at 3 months. Values of changes were performed as mean ± SD or percentage.	
Intervention	A commercially available weight loss programme: A prepackaged, portion-controlled diet plan (PCD) consisted of NutriSystem® D™ PCD 3 months - Women consumed approximately 1250 calories/d: Instructed to consume 3 meals and 1 snack per day from NutriSystem® D™ PCD, added conventional foods - Men consumed approximately 1550 calories/d: With adding other sources, NutriSystem® D™ PCD meals and snacks - Participants received behavioural treatment in groups of 8-12 people, led by health care professional: Weekly from week 1-12, biweekly from week 13-24. Topics included self-monitoring, stimulus control, goal setting and relapse management. - Principal walking: Beginning at week 4, the PCD group participated in 4 sessions of 20 minutes each and progressing by week 24 to 5 sessions of 40 minutes each.	
Comparison/ Control	A diabetes support and education (DSE) programme - Participants attended 3 group sessions of 8-12 people in week 1, 5, 9. - After 12 weeks, participants began weekly comprehensive group behavioural treatment and NutriSystem® D™ PCD in week 1-12. - Principal walking: Beginning at week 16, the DSE group participated in 4 sessions of 20 minutes each and progressing by week 24 to 4 sessions of 40 minutes each.	

Foster 2009 (continued)

Methods	
Outcomes	Primary outcome measures: Weight and BMI changes Secondary outcome measures: WC, BP, HbA_{1C} (glycemic control), glucose, triglycerides, TC and quality of life also presented but not extracted here.
Results	
Participant flow	Did not report
Baseline data	

Table 1: Participants' characteristics at baseline

Measures, mean or n (± SD or %)	PCD, n = 35	DSE, n = 34
Age, years	52.1 (7.7)	52.8 (11.2)
Weight, kg	111.5 (19.3)	110.9 (23.5)
BMI, kg/m^2	39.1 (5.5)	38.9 (6.9)
Gender, n (%)		
Male	9 (25.7)	11 (32.2)
Female	26 (74.3)	23 (67.7)

Patients' characteristics in both groups mostly were female and aged about 52 years with mean weight 111 kg and BMI 39 kg/m^2, approximately.

Number analyzed	ITT: 69 patients (49 females, 20 males), 35 patients in PCD and 34 patients in DSE Completers: 34 patients each in PCD and DSE groups
Outcomes and estimation	

Table 2: Primary outcomes measured at baseline and month 3, completed patients = 68

Measures, mean or n (± SD or %)	PCD, n = 34	DSE, n = 34	*p*-value
Weight, kg			
Baseline	111.5 (19.3)	110.9 (23.5)	
3 months	103.9 (17.6)	110.4 (23.0)	
Adjusted change (range)	-8.2 (9.5 to -6.7)	-0.6 (-2.0 to 0.8)	< 0.0001*
BMI, kg/m^2			
Baseline	39.1 (5.5)	38.9 (6.9)	
3 months	36.6 (5.4)	38.5 (6.8)	
Adjusted change (range)	-2.6 (-3.3 to -1.9)	-0.4 (-1.1 to 0.3)	< 0.0001*

*Significant at $p < 0.05$

Outcomes and estimation	At 3 months, completed patients' mean weight loss (8.2 kg, 7.1%) in PCD group was greater than those in DSE group (0.6 kg, 0.4%) as well as mean BMI (2.6 kg/m^2, 6.6%) in PCD group was greater than those in DSE group (0.4 kg/m^2, 1.0%). Weight loss and BMI decrease of both groups at baseline and 3 months were statistically significant difference ($p < 0.0001$). Patients who participated in a commercially available weight loss programme using a prepackaged, portion-controlled diet plan (PCD) effectively lost weight.

Foster 2009 (continued)

Results	
Adverse events	Did not report
Discussions	
Interpretation	Introduction - Reviewed the increase of obesity and development of diabetes in adults - Described the matter of this study: Few studies about the effects of commercial weight loss programme among obese patients with type II diabetes, and explained the purpose of this study
	Methods Randomised study: Generated sequence of randomisation by random-number generator to a prepackaged, portion-controlled diet plan (PCD) or a diabetes support and education (DSE) programme. Allocated 69 patients (49 females, 20 males) to PCD (35 patients) and DSE (34 patients). Implemented by statistician Blinding was not applicable. Assessing outcomes: Measured weight by calibrated scaled (Detecto, Webb City, MO) with wearing light cloth and without shoes and height by a stadiometer (Harpenden, Holtain Limited, Crosswell, UK). Both were measured twice and presented by the average of the 2 readings at baseline. Should be valid and reliable Providers: Physician, facilitators from ALED and HEED Statistical methods: Although there was no report of the percentage of power calculation, significant level and programme used for analysis, the study presented the tests used. Consequently, SPSS was used, and significant level was $p < 0.001$ and 0.0001 as shown in results.
	Results - No participant flow presented but reported values in mean weight with SD or frequency (%). Both diets reported statistically significant differences ($p < 0.001$ and 0.0001). - At 3 months, the percentage of weight change in PCD group ($7.1 \pm 4\%$) was greater than weight change in DSE groups ($0.4 \pm 2.3\%$). Weight loss of both groups was statistically significant difference between baseline and 3 months ($p < 0.0001$).
	Discussion The authors discussed about comparing weight loss between PCD and DSE programme. At baseline, no significant differences between 2 groups. They commented about participants' characteristics at baseline. Particularly. Their race was that over half were African American who lost less weight than White, likewise other studies. In fact, no need to comment on participants' characteristics because this study did not focus on demographic factors but health risk factors. Thus, it was found that the higher weight loss, the more reduction in HbA_{1c}, WC, BP, triglycerides and quality of life. Nevertheless, findings were clinically and statistically significant difference of PCD group (8.2 kg, 7.1%). Recommendation for further study: Evaluating the effectiveness of this weight loss approach in a clinical setting and a longer time period. Limitations: Short period of the study, inability to disconnect the contact between professional and the PCD group
Generalisability	Did not report
Other evidence	General comments Reported height and weight should be accuracy because of measuring by a calibrated tool and repeating measure. This study suggested that obese patients with type 2 diabetes had profit from the weight loss programme.
Funding	NutriSystem® D™

Gardner 2007[117]

Article identification: 2/2007	Reviewer's initials: SS	Verifier's initials: HB
Author and year: Gardner 2007		Country: US

Objectives	Determined the effects of 4-weight loss diets from low to high carbohydrate intake on weight loss and the related health risk factors among overweight and obese pre-menopausal women
Methods	
Participants	Inclusion criteria: Premenopausal women aged 25-50 years with BMI 27-40 kg/m^2, had stable weight in the last 2 months and stable medications for at least 3 months.
	Exclusion criteria: Women had hypertension, type 1 or 2 diabetes mellitus, heart, renal or liver disease, cancer or active neoplasm, hyperthyroidism, alcohol intake at least 3 drinks/day, medications affect weight or energy expenditure, pregnancy, lactation, no menstrual period in the previous 12 months or plan to be pregnant in the next year.
	Settings and/or locations: Local community in the US
	Duration: 12 months from February 2003 to October 2005
	Recruitment methods: From the local community via media advertisements
	Sample size: 311 participants randomised
Study design	Randomisation-sequence generation: Randomised trial Randomisation in blocks of 24: 6 participants per treatment group 1479 individual screened. 311 randomised.
	Allocation concealment: 77 Atkins group, 79 Zone group, 79 LEARN group, 76 Ornish group
	Implementation: The group assignment from an opaque envelope was chosen by a blinded research technician.
	Blinding: A research technician was blinded for participant selection. Clinic and laboratory staff members were blinded to treatment.
	Statistical methods: 2.7 kg (6 lb or 3% out of 180 lb approximately) was clinically chosen for the minimal significance among group differences in weight change. SD was 6.3 kg of weight change based on the previous study. 80% power was selected to detect a 2.7 kg difference for 12 months. ANOVA was used to analyse the differences of weight changes among 4 diets at month 12. If significant, all pairwise comparisons were tested by using the Tukey studentised range adjustment. Statistical test was 2-tailed using a significant at $p < 0.05$.
Intervention	Participants for each diet group: - Needed to attend 1-hour classes led by a registered dietician once per week for 8 weeks - Were given the incentive payments of $25, $50 and $75 to complete the 2-, 6- and 12-month data collection
Intervention 1	Atkins: Participants received - Diet book of "Dr Atkins' new Diet Revolution". - 20 g/day or less of carbohydrate for induction 2-3 months - 50 g/day or less of carbohydrate for the subsequent "ongoing weight loss" phase The programme was no specific energy restriction goals.

Gardner 2007 (continued)

Methods	
Intervention 2	Zone: Participants received diet book of "Enter the Zone". The programme was a 40%-30%-30% distribution of carbohydrate, protein and fat, respectively and also specific energy restriction goals.
Intervention 3	Ornish: Participants received diet book of "Eat More, Weight Less by Ornish". The programme emphasized on 10% maximum of energy from fat including exercise, nutritional supplements and behavioural modification strategies and also no specific energy restriction goals.
Intervention 4	LEARN: Participants received diet book of "The LEARN Manual for Weight Management". A 16-week programme consisted of 55%-60% energy from carbohydrate and < 10% energy from saturated fat, caloric restriction, increased physical activity and behaviour modification strategies including specific energy restriction goals.
Outcomes	Primary outcome measures: Weight loss Secondary outcome measures: Lipid profile (low- and high-density lipoprotein, non-high-density lipoprotein, cholesterol and triglycerides levels) Percentage of body fat, waist-hip ratio, fasting insulin and glucose levels, BP
Results	
Participant flow	1479 screened: 698 ineligible or not interested, 470 declined to participate or other reasons
	311 randomised: 77 Atkins group: 68 completed, 9 withdrew 79 Zone group: 61 completed, 18 withdrew 79 LEARN group: 61 completed, 18 withdrew 76 Ornish group: 59 completed, 17 withdrew
Baseline data	

Table 1: Participants' characteristics at baseline, mean (± SD)

	Atkins, n = 77	Zone, n = 79	LEARN, n = 79	Ornish, n = 76	All diets, n = 311
Age, years	42 (5)	40 (6)	40 (7)	42 (6)	41 (6)
Weight, kg	86 (13)	84 (12)	85 (14)	86 (10)	85 (12)
BMI, kg/m^2	32 (4)	31 (3)	31 (4)	32 (3)	32 (4)

Participants' characteristics in all diet groups aged 41 years with mean weight 85 kg and BMI 32 kg/m^2.	
Number analyzed	ITT: 77 Atkins group, 79 Zone group, 79 LEARN group, 76 Ornish group

Gardner 2007 (continued)

Results	
Outcomes and estimation	

Table 2: Mean weight and BMI changes from baseline at 12 months, mean (± SD or 95% CI)

	Atkins, n = 77	Zone, n = 79	LEARN, n = 79	Ornish, n = 76	*p*-value
Weight, kg	-4.7 (-6.3 to -3.1) *	-1.6 (-2.8 to -0.4)	-2.2 (-3.6 to -0.8)	-2.6 (-3.8 to -1.3)	< 0.05*
BMI, kg/m^2	-1.65 (2.54)	-0.53 (2.00)	-0.92 (2.00)	-0.77 (2.14)	0.01**

*Significant at $p < 0.05$. ** Significant at $p < 0.01$

At 12 months, Atkins group (81.3 kg, 5.5%) was significantly greater weight loss than others whilst LEARN (82.8 kg, 2.6%), Ornish (83.4 kg, 1.9%) and Zone (82.4 kg, 1.9%) groups lost weight, respectively.

There was statistically significant difference between Atkins and Zone diets ($p < 0.05$). However, there were no statistically significant differences among Zone, LEARN and Ornish.

Secondary outcome	At 12-month changes, HDL-C, triglycerides, SBP and DBP were significant difference at $p = 0.002$, 0.01, < 0.01 and 0.009, respectively. Only Atkins group was the most improvement. Results also presented dietary intake and energy expenditure but not extracted here.
Adverse events	Did not report
Discussions	
Interpretation	Introduction - Reviewed the health cost, health consequence and health benefits of weight loss by National Dietary Weight Loss Guidelines - Described the matter of this study: Had the limited evidence of the effectiveness of other diets, however, no reasons of study population selected premenopausal women - Referred to 4 diets selected in this study which were Atkins (A, very low carbohydrate), Traditional (T, LEARN: Life-style, Exercise, Attitudes, Relationships and Nutrition), Ornish (O, very high carbohydrate) and Zone (Z, low carbohydrate). - Explained 2 objectives of this study
	Methods Randomised trial: Randomisation sequence was generated as blocks of 24. 6 participants per treatment group. 311 participants were randomised and allocated 77 to Atkins group, 79 to Zone group, 79 to LEARN group and 76 to Ornish group. A blinded research technician chose the group assignment from an opaque envelope. Clinic and laboratory staff members were blinded to treatment. Blinding was only investigator side that meant single blind. Participants were not blinded because they might need to know what programme structures were. Comparison of 4 diet groups: Atkins (A, very low carbohydrate), Zone (Z, low carbohydrate), LEARN (T, Life-style, Exercise, Attitudes, Relationships and Nutrition) and Ornish (O, very high carbohydrate). Assessing outcomes: Measured weight to the nearest 0.1 kg on a calibrated clinical scale and height to the nearest ml using a standard wall-mounted stadiometer. Both weight and height values should be valid. Provider: A registered dietician

Gardner 2007 (continued)

Discussions	
Interpretation (continued)	Statistical methods: Reported power calculation (80%) to detect a 2.7-kg difference for 12 months of weight change between 4 treatment groups, at least 75 participants per group. Power calculation could help this study for: 1) Saving time and money, 2) Scanning whether or not participants randomised were enough to see an effect, 3) not wasting time on an underpowered study and 4) preparing for sufficient participants if they declined to participate during the study. Also, reported significant level, values presented and tests used but not programme used. This study used SPSS for data analysis as default from tests used.
	Results - Reported flow of participants with reasons of ineligibility or not interesting, declining to participate or others and withdrawals and also ITT (primary) and completers analysis and values in mean weight with SD - All 4 diet groups reported statistically significant differences at $p < 0.05$, however, there was no report of significant difference among groups at baseline. At 12 months, participants' mean weight loss was 4.7 kg (95% CI, -6.3 to -3.1) in Atkins group, 1.6 kg (-2.8 to -0.4) in Zone, 2.2 kg (-3.6 to -0.8) in LEARN and 2.6 kg (-3.8 to -1.3) in Ornish. There were no statistically significant differences among Zone, LEARN and Ornish. However, there was statistically significant difference between Atkins and Zone diets ($p < 0.05$).
	Discussion The authors commented on women who participated in the diet group by having very low to very high carbohydrate content and discussed the findings. They firstly discussed about concerns on diets that affected blood lipid level and cardiovascular risk. Atkins group was more effective than others because participants in other groups received fat up to 10% in LEARN and Ornish and up to 30% in Zone. As a result, those in other groups less complied. This would affect the primary and secondary outcomes such as LDL-C levels. However, this study did not provide percentages of dietary programme adherence. If so, Atkins would be greater adherence than others. Moreover, Atkins highly decreased TG, SBP and DBP so that this would be associated with cardiovascular risk factors and body weight decrease. Moreover, there were other concerns such as only overweight premenopausal women aged 20-50 years for the initial inclusion criteria of participants and differences in statistical power. Secondly, this study was compared to 2 previous studies of Dansinger and Krauss. Both were similar to this study in a variety of factors. Based on Dansinger's evidence, there were similar in many design features such as numbers and types of treatment groups and the same period of the study. However, there was different report from Dansinger's such as no significant difference among diet groups but only adherence level. This study only reported significant difference between groups at 12 months. Thirdly, comparing to Krauss's study, it was mainly discussed about diets used For example, the different carbohydrate content was compared to fat or protein diets. Lastly, the authors addressed more ideas on greater success in a long-term weight loss programme that depended on increasing energy expenditure, social and environmental supports. There were strengths of this study which were a lager sample size, a long-term treatment and the different diet content in each group. Nevertheless, there were also limitations on only premenopausal women, no considering on menstrual cycle timing, no stability on weight loss trajectories at 12 months and lack of a valid and comparable assessment of individual adherence.
Generalisability	Generalisation to other populations is possibility with caution.
Other evidence	General comments There were more other limitations but not associated with weight loss. Further study: Focus more on health benefits, clinical practice or policy. Physicians are recommended to be counselled to reassure using diets.
Funding	National Institutes of Health

Gold 2007[148]

Article identification: 3/2007	Reviewer's initials: SS	Verifier's initials: HB
Author and year: Gold 2007		Country: US
Objectives	Investigated the effectiveness of a structured behavioural weight loss website (VTrim) vs a commercial weight loss website (eDiets.com)	
Methods		
Participants	Inclusion criteria: Overweight or obese subjects aged 18 years and older with BMI 25-39.9 kg/m^2 and regular access to a computer.	
	Exclusion criteria: Subjects planned to move or get pregnant within the next 12 months, had history of major medical or psychiatric problems, smoked or been a non-smoker < 1 year, took medication affected weight, and were unable to participate the exercise programme weekly meetings.	
	Settings and/or locations: Website weight loss programme	
	Duration: 12 months	
	Recruitment methods: Recruited via advertisement in a local Burlington, VT, newspaper. Also, a technology checked before randomisation, including recruitment by sending and receiving lines of text in a chat programme and submitting entries in an electronic food journal	
	Sample size: 185 participants randomised.	
Study design	Randomisation-sequence generation: Randomised controlled trial, face-to-face intervention. Conducted from February 2003 to March 2005 All subjects were measured at baseline, 6 and 12 months. No further description	
	Allocation concealment: No description 595 eligible participants assessed. 185 participants randomised and allocated to eDiets.com 62 participants, VTrim 62 participants and arm unrelated to this study 61 participants. 124 overweight and obese adults (101 women and 23 men) allocated in the study.	
	Implementation: Did not report	
	Blinding: Did not report	
	Statistical methods: An independent-samples t test was used to compare baseline data between groups for continuous variables as well as χ^2 for categorical variables. Weight change used a baseline-carried-forward (BCF) analysis and completer analysis at 6 and 12 months. Data analysis used SPSS V11.5.	
Intervention	A structured behavioural weight loss website (VTrim): 6-month on-line therapist-led weight loss programme and 6-month on-line weight maintenance programme 6-month weight loss phase: Focused on the modification of eating and exercise habits through the use of behavioural strategies and self-management skills, self-reported their weight each week, chatted on-line in hour-long weekly, asked to reduce energy intake up to 1000 calories/d, instructed to gradually increase energy expenditure and burn minimum of 1000 calories/wk, encouraged peer-to-peer interaction and group support 6-month weight maintenance phase: Provided the same as on-line but less frequency, bi-weekly meeting, encouraged journaling everyday and used the support components of the website	
Comparison/ Control	Commercial weight loss website (eDiets.com): Participants - Participated in a pre-study orientation of the site - Determined how to self-guide their use of the weight loss programme - Were prescribed a calorie goal based on an estimate of their resting metabolic rate - Self-reported weight weekly	

Gold 2007 (continued)

Methods	
Comparison/ Control	This programme: - Provided a calorie-controlled meal plan tailored to individual preferences - Encouraged participants to follow their meal plan (my diet), recipe instructions and menu-specific grocery lists - Supported exercise (my fitness) to provide progress weekly - Monitored by experts and peers in Support central
Outcomes	Primary outcome measures: Weight loss Secondary outcome measures: Social support and use of website components but not extracted here.
Results	
Participant flow	595 eligible participants assessed. 410 excluded. 185 participants randomised and allocated to eDiets.com 62 participants, VTrim 62 participants and arm unrelated to this study 61 participants. 14 and 22 participants lost to follow-up in eDiets.com and VTrim groups, respectively. Completers: 48 participants in eDiets.com and 40 participants in VTrim groups

Table 1: Baseline characteristics of participants in VTrim and eDiets.com groups, n = 62 each

Variable	VTrim, mean (± SD)	eDiets.com, mean (± SD)
Age, years	46.5 (10.7)	48.9 (9.9)
Weight, kg	92.0 (15.7)	90.2 (14.1)
BMI, kg/m^2	32.3 (3.9)	32.5 (4.2)
Sex, n (%)		
Female	48 (77)	53 (86)
Male	14 (23)	9 (15)

Patients' characteristics in both groups were 80% of women with mean aged about 47 years, mean weight 91 kg and mean BMI 32 kg/m^2, approximately.	
Number analyzed	ITT: 62 participants each in eDiets and VTrim groups Completers: 48 participants in eDiets.com and 40 participants in VTrim groups
Outcomes and estimation	Primary outcome: Weight loss at month 6 with ITT analysis, VTrim lost more weight than eDiets.com group (6.8 ± 7.8 kg vs 3.3 ± 5.8 kg, $p = 0.005$ or 7.3 ± 7.8 % vs 3.6 ± 6.1%). At month 12 with BCF analysis, VTrim also lost more weight than eDiets.com group (5.1 ± 7.1 kg vs 2.6 ± 5.8 kg, $p = 0.034$ or 5.5 ± 7.6% vs 2.8 ± 5.5%). As a result, patients in a therapist-led structured behavioural weight loss website were greater weight loss than a self-help commercial weight loss website. Weight loss at month 6 with completers analysis, VTrim lost more weight than eDiets.com group (8.3 ± 7.9 kg vs 4.1 ± 6.2 kg, $p = 0.004$ or 8.9 ± 7.8% vs 4.4 ± 6.5%). At month 12, VTrim also lost more weight than eDiets.com group (7.8 ± 7.5 kg vs 3.4 ± 5.8 kg, $p = 0.002$ or 8.6 ± 7.9% vs 3.7 ± 6.0%). As a result, patients in a therapist-led structured behavioural weight loss website lost weight 5% or more of their initial body weight.
Adverse events	Did not report

Gold 2007 (continued)

Discussions	
Interpretation	Introduction - Reviewed the proportion of prevalence of US overweight and obesity, the incidence related, health costs on overweight and obesity, the principle of treatment in obesity and total number and percentage of US people who can access Internet. - Reviewed the relevant studies about the Internet research-based weight loss intervention studies and presented findings from the previous studies - Reviewed the drawback of the effects of on-line weight loss programmes - Described the matter of this study: Little knew about the effectiveness of on-line weight loss programme - Explained 2 aims of this study, however, in this review study focused only on the primary purpose that was compared a behavioural on-line intervention to a commercial self-help website on weight loss
	Methods Randomised controlled trial, face-to-face intervention: No report of what type of randomisation used. However, allocation numbers were existed by following: 595 eligible participants were assessed. 185 participants were randomised and allocated to eDiets.com 62 participants, VTrim 62 participants and arm unrelated to this study 61 participants. 124 overweight and obese adults (101 women and 23 men) were allocated in the study. Implementation and blinding were not applicable. Assessing outcomes: Measured weight by a beam-balance scale with their street clothes and no shoes and height with self-reported at baseline. Weight value should be valid whilst height may be under of over estimation. Provider: Therapist Statistical methods: No report of power calculation and significant level, however, this study presented type of analysis, tests used, programme analysed and 2 analyses which were BCF and completers analysis There was no power calculation to: 1) Detect the difference between baseline and the end of programme, 2) scan whether or not participants randomised were enough to see an effect and 3) prepare for sufficient participants if they declined to participate during the study.
	Results - No report for significant level in the statistical methods, significant level at $p < 0.05$ was regularly selected as default. - Reported flow diagram of the study participants, number of ITT and completers analysis and values in mean weight with SD. Both weight loss programmes reported statistically significant differences at $p < 0.05$. - At month 6 with completers analysis, VTrim lost more weight than eDiets.com group (8.3 ± 7.9 kg vs 4.1 ± 6.2 kg, $p = 0.004$). At month 12, VTrim also lost more weight than eDiets.com group (7.8 ± 7.5 kg vs 3.4 ± 5.8 kg, $p = 0.002$). As a result, patients in a therapist-led structured behavioural weight loss website lost weight 5% or more of their initial body.
	Discussion The authors summarised on the findings of this study. At the first 6 months, weight change of both groups was associated with web usage. However, at the last 6 months, both groups gained weight because of decreasing web usage. They also discussed by comparing to the 2 previous on-line weight loss studies. However, it was uncertain that whether or not the effective weight loss was managed by the quality of weight loss programme. As a consequence, the on-line weight loss programme was compared to university-based on-line programmes. Findings were similar but not yet known about whether or not the on-line programmes with a larger population were feasible or economical. Nonetheless, during the time period of this study, this study informed that eDiets.com charged $99.00 for a 1-year membership. VTrim would be more expensive than eDiets.com.

Gold 2007 (continued)

Discussion	
	Discussion (continued) Strengths: 1) Randomised controlled trial with the weight data was the first study of investigating a commercial online weight loss programme without relating additional professional contact. 2) Comparing to a traditional face-to-face programme, subjects who involved an online structured behaviour weight loss website could achieve their weight loss. Subjects who received a structured, therapist-led behavioural online weight loss programme significant lost more weight than those who enrolled a self-help commercial weight loss programme. The percentage of subjects' weight loss in the structured programme mostly doubled achieving a 5% or more weight loss target, 65% vs 37.5%.
Generalisability	Did not report
Other evidence	General comments Recommendation for further study: Repeat the study on a larger scale and investigate the feasibility of a more structured behavioural programme by incorporating and applying into a commercial programme An online weight loss website, therapist-led structured behavioural intervention was greater weight loss than a self-help commercial online weight loss programme. The reason was that commercial weight loss website had enormous potential public health impact.
Funding	US Department of Agriculture Health Act Funds

Green 2005[149]

Article identification: 2/2005	Reviewer's initials: SS	Verifier's initials: HB
Author and year: Green 2005		Country: UK, US
Objectives	Investigated whether the working memory impairments characteristics of dieting were related to cortico-steroid secretion in the early stages of weight loss	
Methods		
Participants	Inclusion criteria: Participants who were healthy, pre-menopausal and overweight women with BMI 25-29 kg/m^2 aged 20-45 years with normal or corrected to normal, visual acuity and English as the first language.	
	Exclusion criteria: Participants with physical or psychiatric health problems, smokers, heavy drinkers, taking dietary supplements or oral contraceptive, pregnancy or lactating	
	Settings and/or locations: Birmingham, UK	
	Duration: 8 weeks	
	Recruitment methods: Recruited via newspaper advertisement 336 potential participants completed the initial telephone and a postal health screening.	
	Sample size: 73 participants randomised	
Study design	Randomisation-sequence generation: Randomised controlled trial. 73 participants randomised. No further description	
	Allocation concealment: Insufficient information 16 participants in control group, 25 participants in unsupported dieters and 14 participants in supported dieters	
	Implementation: Did not report	
	Blinding: Did not report	
	Statistical methods: Analysed data via SPSS V11 by using mean ± standard error (SE), significant at $p < 0.05$	
Intervention 1	Supported dieters: Commercial weight loss plan consisted of: calorie restriction, nutritionally balanced diet in conjunction with weekly weighing and group support sessions but without food provided.	
Intervention 2	Unsupported dieters: Participants were asked to pursue any diet plan selected. The diets selected ranged from the nutritionally balanced or calorically restricted diets, low fat diets and low carbohydrate diets	
Comparison/ Control	Non-dieting control All participants attended weekly weighing sessions.	
Outcomes	Outcome measures: Changes in BMI and body weight Other outcome measures: Cortisol secretion, neuropsychological assessment and state anxiety but not extracted here.	
Results		
Participant flow	Did not report	

Green 2005 (continued)

Baseline data, outcomes and estimation

Table 1: Difference of mean BMI and body weight at baseline, week 1, 4 and 8

	Control group, n = 16	Unsupported dieters, n = 25	Supported dieters, n = 14
BMI, kg/m^2			
Baseline	26.88 (6.52)	28.15 (4.10)	29.27 (6.52)
Week 1	0.00 (0.14)	-0.34 (0.22)	-0.37 (0.08)
Week 4	0.03 (0.20)	-0.50 (0.40)	-0.59 (0.23)
Week 8	0.10 (0.35)	-0.86 (1.02)	-0.97 (0.41)
Body weight, kg			
Baseline	74.12 (162.95)	75.09 (83.52)	80.42 (94.28)
Week 1	-0.25 (1.17)	-0.79 (1.12)	-1.00 (0.54)
Week 4	-0.13 (1.49)	-1.26 (2.82)	-1.62 (1.95)
Week 8	-0.05 (2.84)	-2.16 (7.24)	-2.65 (3.28)

Notes: Data presented the baseline measurements and subsequent change from baseline, mean (± SE)

Table 1: There was no significant difference between baseline and other time within group. On the other hand, there was significant difference among groups.

Both unsupported (2.9%) and supported dieters (3.3%) were higher weight loss than control group (0.07%). However, comparing between unsupported and supported dieters was greater weight loss in the unsupported dieters.

Number analyzed	ITT: Did not report, 55 participants completed Completers: 16 participants in control group, 25 participants in unsupported dieters and 14 participants in supported dieters
Adverse events	Did not report
Discussions	
Interpretation	Introduction - Reviewed the proportion of prevalence of UK overweight and obesity, NHS plan the management and prevention of obesity - Reviewed the relevant studies about dieting helped weight loss, factors related successful weight loss such as age and starting weight, psychosocial status, cognitive function - Reviewed the impairment form cognitive function such as diets in unsupervised and uncontrolled manner or supervised and supported individuals - Hypothesis was that the observed impairment in cognitive function, an elevated stress response was occurred during the first stage of unsupported dieting. This hypothesis was supported by the previous studies. However, those studies were not clarified whether or not these impairments were a function of unsupported or supported dieting. Therefore, the matter of this study was compared a function of supervised to unsupervised dieting and raised cortico-steroid levels. - Explained aim of this study

Green 2005 (continued)

Discussions	
Interpretation (continued)	Methods Not applicable for randomisation-sequence generation, allocation concealment, implementation, blinding, ITT and sample size or power calculation There was no power calculation to: 1) Detect the difference between baseline and the end of programme, 2) scan whether or not participants randomised were enough to see an effect and 3) prepare for sufficient participants if they declined to participate during the study. The study was RCT but did not report how to generate and who implemented randomisation. However, the study presented 73 participants were randomised. 16 participants in control group, 25 participants in unsupported dieters and 14 participants in supported dieters. Comparison of 3 groups: Control, unsupported dieters and supported dieters groups Assessing outcomes: Measured weight in underwear and without shoes by using the foot-to-foot electronic scale (TBF-350A, Tanita Corp., Tokyo, Japan) and height by using a wall mounted stadiometer. Both values should be valid. Provider: Dietician Statistical methods: Although statistical analysis was not in the methods section, tests used, programme analysed, values presented and significant level were presented in the first paragraph of results. Nevertheless, there was no report of power calculation to detect differences of sample size each group at the particular time point.
	Results - No report of participant flow, however, reported values in mean weight with SE - All 3 groups reported statistically significant differences at $p < 0.05$. - At 8 weeks, supported dieters (3.3%) were greater weight loss than unsupported dieters (2.9%). However, the sample size of both dieters was small and short period of the treatment. The duration of weight loss should be long-term treatment for the future work.
	Discussion The authors summarised the present study, referred to the previous data of Green about the neuropsychological impairments and compared to the similar study about the cortisol levels. Reviewer emphasized only on weight loss so that supported dieters were greater weight loss than unsupported dieters. Nevertheless, authors discussed about uncertainty of the relationship between stress, cortisol, unsupported dieting and cognitive function. Authors discussed about confounding variables that was the possibility of confounding variables such as depression could affect the differences of the cognitive function. This may be for the further research by assessing the influence of confounding variables
Generalisability	Did not report
Other evidence	General comments Limitations: Small sample size, short-term treatment Further study: Larger sample size and long-term study
Funding	US Department of Agriculture

Haapala 2009[124]

Article identification: 2/2009	Reviewer's initials: SS	Verifier's initials: HB
Author and year: Haapala 2009		Country: Finland
Objectives	Investigated the short- and long-term effectiveness of weight loss in a mobile phone weight-loss programme in healthy overweight adults	
Methods		
Participants	Inclusion criteria: Overweight healthy adults aged 25-44 years with BMI 25-36 kg/m^2, accessed to a mobile phone and Internet connection.	
	Exclusion criteria: Participants aged younger than 18 years with BMI < 18 kg/m^2, were diagnosed as a chronic disease, and had major psychiatric disease and plan or previous pregnancy within 6 months	
	Settings and/or locations: University hospital, Kuopio Finland	
	Duration: 1 year from June 2001 to 2002	
	Recruitment methods : Recruited subjects via newspaper advertisement and telephone screening 156 eligible via telephone screening	
	Sample size: 125 subjects randomised.	
Study design	Randomisation-sequence generation: Randomised controlled study The sample size was selected 20% ineligible subjects and 30% attrition rate to detect effects at $\alpha = 0.05$ with 80% power. 156 subjects were eligible via telephone screening. 125 subjects randomised. No further description	
	Allocation concealment: Insufficient information 62 subjects in experimental group and 63 subjects in control group	
	Implementation: Nurse implemented randomisation and was blinded gender.	
	Blinding: Nurse blinded	
	Statistical methods: Using repeated-measures ANOVA was to test changes in continuous-dependent variables with normal distribution. ITT analysis used for weight at baseline. Values presented as mean ± SD. Data analysis used SPSS V10.0.5.	
Intervention	Mobile phone-operated weight-loss programme, Weight Balance® - Instructed a staggered reduction of food intake and daily weight reporting with immediate tailored feedback - Calculated the dieter's daily energy requirement and physical activity - Received information on the dieter's current weight - Consumed the amount of food in proportion of subject's normal weight - Based on text message so that no phone calls - Encouraged reducing food intake but increasing in daily physical activity - Website provided a personal password-protected keeping dietary record and tracking individual's weight loss - Assessed at baseline, 3 (with control), 6, 9 and 12 (with control) month - Allowed dieters to target their weight goal with a short- or long-term at every 3-month visit - Started weight loss at 2 kg/month and could use this programme for weight-loss maintenance	
Comparison/ Control	Control: No intervention, but offered the studied weight-loss programme free of charge after the 12-month visit. No specific instruction on diet or exercise	

Haapala 2009 (continued)

Methods	
Outcomes	Primary outcome measures: Weight change Secondary outcome measures: User satisfaction but not extracted here
Results	
Participant flow	156 subjects were eligible. 31 subjects excluded. 125 subjects randomised. 62 subjects in experimental group and 63 subjects in control group. Experimental group: Completers at 3, 6, 9 and 12 months were 56 (6 excluded), 45 (17 excluded), 45 (17 excluded) and 45 (17 excluded) subjects, respectively. Control group: 1 subject excluded. At 12 months, completers were 40.

Table 1: Subjects' characteristics at baseline

Demographics, mean or n (± SD or %)	Experimental group, n = 62	Control group, n = 62
Age, years	38.1 (4.7)	38.0 (4.7)
Weight, kg	87.5 (12.6)	86.4 (12.5)
BMI, kg/m^2	30.6 (2.7)	30.4 (2.8)
Gender, n (%)		
Male	13 (21.0)	15 (24.0)
Female	49 (79.0)	47 (76.0)

Subjects' characteristics in both groups were about 77% of female, aged 38 years and had mean weight 87 kg and mean BMI 30 kg/m^2, approximately.

Number analyzed	ITT: 62 subjects each in experimental and control groups Completers: At 12 months, 42 subjects in experimental group and 40 subjects in control group

Outcomes and estimation

Table 2: Primary outcomes measured at baseline, month 3 and month 12, mean (± SD)

Variable	Baseline	3 months	12 months
Body weight, kg*			
EG**, n = 42	86.6 (12.7)	82.0 (12.9)	82.1 (14.1)
CG***, n = 40	85.1 (12.5)	-	84.0 (13.2)
Weight loss, %****			
EG*, n = 42	-	5.3 (3.5)	5.4 (5.8)
CG**, n = 40	-	-	1.3 (6.5)

* For EG, significant at $p = 0.006$ level from baseline at each time point.

** EG = Experimental group. *** CG = Control group.

Outcomes and estimation	At 12 months, the completed subjects' mean weight loss in experimental group (4.5 kg, 5.4%) was greater than control group (1.1 kg, 1.3%). As a result, weight loss between groups at 12 months was statistically significant difference ($p = 0.006$). Therefore, the mobile phone-operated weight-loss programme, Weight Balance® was effective in a 1-year study.
Adverse events	Did not report

Haapala 2009 (continued)

Discussions	
Interpretation	Introduction - Reviewed the innovative and attractive toll for weight loss programme such as Internet, email and mobile phone, and also reviewed the relevant studies on the efficacy of Internet-based weight loss programme compared with traditional programme and also theory related that was shown in the flow of contingency model in mobile phone weight loss - Described the matter of this study: The mobile phone weight loss programme was a new programme and necessary to be reported. Explained the purpose of this study
	Methods Randomised controlled study: The sample size was selected 20% ineligible subjects and 30% attrition rate to detect effects at $\alpha = 0.05$ with 80% power. 125 subjects were randomised and allocated 62 subjects to experimental group and 63 subjects to control group. Nurse implemented randomisation and was blinded gender. Comparison of 2 weight loss groups: Experiment (mobile phone weight loss) and control groups. At baseline, no statistically significant differences. Assessing outcomes: Measured weight and height by nurses but no report of using any scale. Both values could be acceptable. Provider: Nurse Statistical methods: Reported power calculation, tests used, programme analysed, ITT and completers analysis, however, *p*-value was in results. Power calculation could help this study for: 1) Detecting effects to scan whether or not participants randomised were enough to see an effect and 2) preparing for sufficient participants if they declined to participate during the study.
	Results - Presented participant flow that consisted of numbers of eligible, randomised, excluded and completed participants including the percentage of discontinued participants and reasons. Reported values in mean weight with SD - Both groups reported statistically significant differences at several *p*-value, however, every value was < 0.05. At baseline, there were no significant differences in main outcomes. At 12 months in completers analysis, participants' mean weight loss in experimental group (4.5 kg) was significantly greater than control group (1.1 kg) at $p = 0.006$. This new programme, the mobile phone-operated weight-loss programme, was effective in a long-term study.
	Discussion The authors summarised findings of the present study, supported this study by the previous research and suggested the major factor of using this programme (self-reported) and the further research. There were limitations that could be considerable in the future. Limitations: 1) May overestimate results of 12 months because of the quarterly weight-ins, 2) Use individually data report by using a self-administered questionnaire for physical activity and dietary habits, 3) Cannot validate measures of energy-dense foods in the Finnish population at the time of study. In conclusion, weight loss by mobile phone delivery was considerably effective for supporting the short- (3 months) and long-term (12 months). Weight loss depended on the amount and type of programme used and learning the behavioural and self-efficacy changes. The more programme contacted, the more weight loss positive. For long-term reduction in weight, the intervention group was equal to or greater than the minimal contact programme. The higher text message reported frequently, the greater percentage weight lost at 12 months of the initial weight.
Generalisability	Did not report
Other evidence	General comments Recommendation for further study: May require the longitudinal studies.
Funding	GeraCap Invia Ltd, producer of the Weight Balance®

Heshka 2000[151]

Article identification: 1/2000	Reviewer's initials: SS	Verifier's initials: HB
Author and year: Heshka 2000		Country: US

Objectives	Compared the effects of a self-help programme and a commercial programme on weight loss in overweight and obese men and women
Methods	
Participants	Inclusion criteria: Men and women aged 18-65 years with BMI 27-40 kg/m^2 and had health problems for eligibility of weight reduction.
	Exclusion criteria: Men and women with: - Fasting glucose level > 140 mg/dL, triglyceride level > 1,000 mg/dL - A serum aspartate aminotransferase, alanine aminotransferase, alkaline phosphatase, lactate dehydrogenase, gamma glutamyltransferase or bilirubin level > twice the upper limit of normal level - A serum creatinine level > 1.4 mg/dL - Using systemic or inhaled corticosteroids or lithium - History of alcohol abuse within last year, any significant psychiatric disorder or others condition that interfere the weight loss programme - Taking a new drug therapy within 30 days and attending the programme - Taking prescription medicines for weight loss within 90 days
	Settings and/or locations: Multicentre (6 clinical research centres)
	Duration: 26 weeks
	Recruitment methods: Recruited from the list of former participants in the programme and advertised for a long-term nonmedication weight loss study in moderately overweight people - Interviewed, signed inform consent and underwent screening procedures
	Sample size: 423 subjects randomised (358 women, 65 men)
Study design	Randomisation-sequence generation: Randomised controlled study by blocking each block 2-10. Determined blocking by a random number table
	Allocation concealment: Data-coordinator prepared randomisation envelope and opened this to inform the eligible participants to be assigned to the self-help or the commercial programme. Randomised 70 subjects per site 211 subjects in commercial programme, 212 subjects in self-help group
	Implementation: No description
	Blinding: Did not report
	Statistical methods: Used ANOVA or ANCOVA to test hypotheses of greater changes in the commercial programme than in the self-help group Significant at 0.05 (2-sided), used chi-squared test to compare proportions of both groups, reported by mean ± SD Data analysis used SAS V6.12 and SPSS V8.0

Heshka 2000 (continued)

Methods			
Intervention	Commercial programme (Weight Watchers, WW): Subjects had - Vouchers cost $9.00 to attend WW sessions - Their own choice for any meeting location and time - Instruction of participating in a research study - A food plan: A nutritionally balanced and moderate diet designed to produce a weight loss up to 0.9 kg for a week. - An activity plan: Followed current guidelines - A behaviour-modification plan: Group and social support		
Comparison/ Control	Self-help programme: Subjects had - 20-minute consultations with a dietician at the first session and week 12 visits - The printed material orientation for dietary principles and physical activity guidelines on weight loss - Other resources offering weight loss information such as public library materials, web sites on the Internet and telephone number of health promotion organisations		
Outcomes	Outcome measures: Weight and BMI changes Other outcome measures: WC and body fat were not extracted here.		
Results			
Participant flow	Did not report		
Baseline data	Table 1: Subjects' characteristics, mean (± SD) or number (%)		
		Commercial programme, n = 211	Self-help group, n = 212
	Age, years	45 (10)	44 (10)
	Weight, kg	94.2 (13.1)	93.1 (14.4)
	BMI, kg/m^2	33.8 (3.4)	33.6 (3.7)
	Participants' characteristics in both groups aged about 44.5 years with mean weight 93.7 kg and mean BMI 33.7 kg/m^2, approximately.		
Number analyzed	ITT with missing data replaced by last observation carried forward (LCF). ITT: 211 subjects in commercial programme, 212 subjects in self-help group Completers: 174 subjects in commercial programme, 172 subjects in self-help group		

Heshka 2000 (continued)

Results

Outcomes and estimation

Table 2: Comparison of weight changes (kg) over time, mean (± SD)

	Commercial programme	Self-help group	Difference (95% confident interval)
ITT analysis	n = 211	n = 212	
Week 0-12	-3.9 (3.7)	-1.3 (3.2)	2.6 (1.9-3.3)
Week 12-26	-0.9 (2.8)	-0.1 (2.6)	0.8 (0.3-1.3)
Week 0-26	-4.8 (5.6)	-1.4 (4.7)	3.4 (2.4-4.4)
Available cases	n = 174	n = 172	
Week 0-12	-4.6 (3.4)	-1.6 (3.4)	3.0 (2.3-3.7)
Week 12-26	-1.1 (2.9)	-0.2 (2.9)	0.9 (0.3-1.5)
Week 0-26	-5.7 (5.7)	-1.7 (5.0)	4.0 (2.9-5.1)

At 26 weeks for ITT analysis, participants' mean weight loss in commercial programme (4.8 kg, 5.0%) was greater than self-help group (1.4 kg, 1.5%) as well as available cases, participants' mean weight loss in commercial programme (5.7 kg, 6.0%) was greater than self-help group (1.7 kg, 1.8%). The differences of weight changes between groups were 3.4 for ITT analysis and 4.0 for available cases.

At 26 weeks, mean BMI in commercial programme decreased to 32.1 kg/m^2 (-1.7 ± .19 kg/m^2) whilst in self-help group was 33.1 kg/m^2 (-0.5 ± 1.6 kg/m^2).

Table 3: Percentage of weight changes by treatment group[a], number (%)

	Commercial programme, n = 174	Self-help group, n = 172
Decrease from initial weight		
10% or more	44 (25)*	13 (8)
5% - 10%	48 (28)*	13 (8)
0 – 5%	57 (33)**	82 (48)
Increase from initial weight		
0 – 5%	24 (14)*	57 (33)
5% - 10%	1 (1)	6 (3)
10% or more	-	1 (1)

[a]Percentages do not add to 100 because of rounding error.

*Significant at $p < 0.01$, **Significant at $p < 0.05$

At 26 weeks, participants in commercial programme who lost weight over 5% of their entry weight were 53% whereas those in self-help groups were 16%. There was also statistically significant difference between groups ($p < 0.01$).

Adverse events	Did not report

Heshka 2000 (continued)

Discussions	
Interpretation	Introduction - Reviewed the adverse effect of traditional weight loss programme, the proportion of US adults who participated in the weight loss programme. However, the literature review showed concerns about other changes if participants participated in either commercial or self-help weight loss programme. - Described the matter of this study: The first evaluating of a long-term, multicentre, randomised trial in the largest provider of commercial weight loss programme in the US. Explained objectives of this study
	Methods Randomised controlled study by blocking each block 2-10. Data-coordinator prepared randomisation envelope and opened this to inform the eligible participants to be assigned to the self-help or the commercial programme. 423 subjects were randomised. However, 70 subjects were randomised per site and allocated 211 subjects in commercial programme and 212 subjects in self-help group. Determined blocking by a random number table Blinding was not applicable. Comparison of 2 groups: Commercial and self-help groups. At baseline, no statistically significant differences. Assessing outcomes: Measured weight to the nearest 0.1 kg in street clothing with no shoes on a calibrated scale. Weight value should be valid. Provider: Dietician Statistical methods: No report of power calculation, however, this study reported tests used and 2 programmes analysed, significant level, ITT analysis with missing data replaced by LOCF and values presented. There was no power calculation to detect a difference between baseline and the end of treatment in order to scan whether or not participants randomised were enough to see an effect and to prepare for sufficient participants if they declined to participate during the study.
	Results - Although there was no report of participant flow, ITT and completers analysis were reported. Values in mean weight with SD and 95% CI were reported. Both groups reported statistically significant differences at $p < 0.05$ or 0.01 to strongly significant difference. At baseline, there were no statistically significant differences between groups. - At 26 weeks for ITT analysis, participants' mean weight loss in commercial programme (4.8 kg) was greater than self-help group (1.4 kg) as well as mean BMI in commercial programme decreased to 32.1 kg/m^2 (-1.7 kg/m^2) whilst in self-help group was 33.1 kg/m^2 (-0.5 kg/m^2) at $p < 0.001$.
	Discussion The authors summarised findings of this study mainly focused on commercial weight loss results and also referred to WW study. At the same duration of 12 weeks, WW lost weight only 2.2 kg with 30% of the original subjects, and another recent study lost 6.1 kg with 75% of the subjects remained. Comparing to this study, subjects lost weight 4.6 kg by self-reporting with 80% of the baseline subjects. Authors claimed that results of weight changes were similar to other studies in terms of weight loss at 12 weeks. For other measures, findings were uncertain. Reviewer only concluded weight change. The CWLP had greater weight loss than the self-help group for 26-week weight loss programme.
Generalisability	No generalisability because of one particular CWLP with many unique aspects but not many commercial programmes
Other evidence	General comments Recommendation for further study: Should measure other outcomes such as serum and vitamin levels, and any variables associated with cardiovascular disease
Funding	The Weight Watchers Foundation

Heshka 2003[150]

Article identification: 1/2003	Reviewer's initials: SS	Verifier's initials: HB
Author and year: Heshka 2003		Country: US

Objectives	Compared weight loss and health benefits achieved and maintained between self-help programme and a structured commercial programme
Methods	
Participants	Inclusion criteria: Men and women aged 18-65 years with BMI 27-40 kg/m^2 and were persons with health problems.
	Exclusion criteria: Participants had - Fasting glucose > 140 mg/dL/7.8 mmol/L, triglycerides > 1000 mg/dL/11.3 mmol/L, liver function test, used systemic and inhaled corticosteroids or lithium - A history of alcohol abuse within the past year, psychiatric disorder - A new drug therapy within 30 days of randomisation - Prescription weight loss within 90 days
	Settings and/or locations: 6 US clinical centres
	Duration: 2 years from January 1998 to 2001
	Recruitment methods: Recruited from the existing clinic records or via advertising a long-term nonmedication weight loss study
	Sample size: 423 participants randomised (65 men, 358 women)
Study design	Randomisation-sequence generation: Multicentre randomised controlled trial Blocking was used for randomisation by a random number table.
	Allocation concealment: The envelopes prepared was opened. 484 participants were eligible. 423 participants randomised. 211 participants for commercial group, 212 participants for self-help group. For completers at 2 years, 150 participants for commercial group, 159 participants for self-help group.
	Implementation: Investigators implemented the condition assigned by opening the envelopes prepared.
	Blinding: Double-blind. Participants and investigators at each site were blinded to 2 groups assigned.
	Statistical methods: Independent t tests for continuous variables and Fisher exact test for categorical variables used to compare differences between groups by following ITT analysis (included all randomised participants), a modified ITT analysis (included all participants who made at least 1 clinic visit after randomisation) and completers analysis (only participants who completed the study). Values reported as mean ± SD with statistical significance at $p < 0.5$. Data analysis used SAS V8.
Intervention	Structured commercial weight loss programme: Gave vouchers to attend Weight Watchers sessions, programme consists of food, activity and behaviour plans Food plan: Nutrition balance, Activity plan: Followed NIH guidelines by weekly group meetings of an hour's duration, Behaviour plan: Self-reported attendance
Comparison/ Control	Self-help group: Received 20-minute consultations with dietician at baseline and week 12, dietary principles and exercise guidelines for safe weight loss Free offered information from public library materials, Web sites and telephone numbers of health promotion organisations

Heshka 2003 (continued)

Methods	
Outcomes	Primary outcome measures: Weight change Secondary outcome measures: BP, TC, HDL-C, triglycerides, insulin, glucose, quality of life and adverse events
Results	
Participant flow	484 participants were eligible. 61 participants excluded. 423 participants randomised. 211 participants were assigned to commercial group. 212 participants were assigned to self-help group. 61 participants lost to follow-up in commercial group. 53 participants lost to follow-up in self-help group. 150 participants completed the commercial group. 159 participants completed the self-help group. 198 participants included in modified ITT analysis in commercial group. 188 participants included in modified ITT analysis in self-help group. 148 participants included in completers analysis in commercial group. 2 participants excluded from the commercial group. 159 participants included in completers analysis in self-help group.

Table 1: Participants' baseline characteristics*

Variables	Commercial group ,n = 211	Self-help group, n = 212
Age, years	45 (10)	44 (10)
Women, n (%)	173 (82)	185 (87)
Weight, kg	94.2 (13.1)	93.1 (14.4)
BMI, kg/m^2	33.8 (3.4)	33.6 (3.7)

*Values shown are mean (± SD). There were no statistically significant differences between 2 groups.

Patients' characteristics in both groups were about 85% of women, aged 44.5 years and had mean weight 93.7 kg and BMI 33.7 kg/m^2, approximately.

Number analyzed	ITT: 211 participants were assigned to commercial group. 212 participants were assigned to self-help group. Completers: 150 participants completed the commercial group. 159 participants completed the self-help group.

Heshka 2003 (continued)

Results						
Outcomes and estimation						
Table 2: Weight and BMI changes at year 1 and 2						
	Year 1[a]			Year 2[b]		
	Commercial group	Self-help group	*p*-value	Commercial group	Self-help group	*p*-value
Weight[*], kg [Mean (± SE)]						
Intention-to-Treat	-4.3 (0.4)	1.3 (0.4)	<0.001	-2.9 (0.5)	-0.2 (0.4)	<0.001
Completers	-5.0 (0.5)	-1.4 (0.5)	<0.001	-3.0 (0.6)	-0.1 (0.6)	<0.001
Decreased from initial weight, n (%)	n = 172	n = 170		n = 148	n = 159	
≥ 10	37 (21)	15 (9)	0.002	24 (16)	9 (6)	0.005
> 5-< 10	29 (17)	19 (11)	0.15	27 (18)	24 (15)	0.57
0-5	68 (39)	57 (33)	0.37	42 (28)	46 (29)	> 0.99
BMI[*], kg/m^2 [Mean (SE)]						
Intention-to-Treat	-1.6 (0.2)	-0.5 (0.2)	<0.001	-1.1 (0.2)	-0.2 (0.2)	<0.001[c]
Completers	-1.9 (0.2)	-0.6 (0.2)	<0.001	-1.2 (0.2)	-0.1 (0.2)	<0.001[c]
[a]$p < 0.01$ for hypothesis of similar frequency distribution in the 2 groups.						
[b]$p = 0.002$ for hypothesis of similar frequency distribution in the 2 groups.						
[c] Value is significantly different from baseline at $p < 0.05$.						
[*]Participants to measure weight and BMI for ITT analysis were 211 in commercial group and 212 in self-help group whilst participants for completers analysis were 148 in commercial group and 159 in self-help group.						
At 1 year, the ITT participants' mean weight loss in commercial group (4.3 kg, 4.6%) was greater than self-help group (1.3 kg, 1.4%) as well as BMI in commercial group (1.6 kg/m^2) decreased more than self-help group (0.5 kg/m^2).						
For the completers, participants' mean weight loss in commercial group (5.0 kg, 5.3%) was greater than self-help group (1.4 kg, 1.5%) as well as BMI in commercial group (1.9 kg/m^2) decreased more than self-help group (0.6 kg/m^2).						
Weight loss between groups was statistically significant difference at $p < 0.01$.						
Of 38% of participants in commercial group lost weight at least 5% of their initial weight whereas only 20% of participants in self-help group lost weight at least 5% of their initial weight.						
At 2 years, the ITT participants' mean weight loss in commercial group (2.9 kg, 3.1%) was greater than self-help group (0.2 kg, 0.2%) as well as BMI in commercial group (1.1 kg/m^2) decreased more than self-help group (0.2 kg/m^2).						
For the completers, participants' mean weight loss in commercial group (3.0 kg, 3.2%) was greater than self-help group (0.1 kg, 0.1%) as well as BMI in commercial group (1.2 kg/m^2) decreased more than self-help group (0.1 kg/m^2).						
Weight loss between groups was statistically significant difference at $p < 0.002$.						
Outcomes and estimation	Of 34% of participants in commercial group lost weight at least 5% of their initial weight whereas 21% of participants in self-help group lost weight at least 5% of their initial weight. As a result, a structured commercial programme was more effective than the self-help group for participants who participated in the weight loss programme over a 2-year period.					

Heshka 2003 (continued)

Results	
Secondary outcome	At 2-year changes in WC ($p = 0.003$), there was significant difference in the commercial group whilst changes in BP, lipids, glucose and insulin levels in both groups were not significant differences, respectively. Results also quality of life but not extracted here.
Adverse events	Reported as no adverse events to withdraw people from the study
Discussions	
Interpretation	Introduction - Reviewed the number increasing of US adults who attempted to lose weight and described the percentage of adults who participated in the weight loss programme. However, the literature review showed that obese participants seldom succeed a normal range of BMI. As a result, commercial weight loss programmes were recommended. - Described the matter of this study: The previous study showed that the effects of commercial weight loss programme on weight loss were seldom evaluating, and there were no studies conducted 2-year multicentre randomised trial. - Explained objectives of this study
	Methods Multicentre randomised controlled trial: Randomisation-sequence generation used blocking from a random number table. 423 participants were randomised and allocated 211 participants to commercial group and 212 participants to self-help group. Investigators implemented the condition assigned by opening the envelopes prepared. This study was double-blind because participants and investigators at each site were blinded to 2 groups assigned. Comparison of 2 groups: Commercial and self-help groups. At baseline, no statistically significant differences. Assessing outcomes: No report of measuring weight and height. Hence, both weight and height values could be over or under estimation. Provider: Dietician Statistical methods: No report of power calculation, however, this study reported tests and programme used, significant level, ITT and completers analysis and values presented. There was no power calculation to detect a difference between baseline and the end of treatment among 3 groups in order to scan whether or not participants randomised were enough to see an effect and prepare for sufficient participants if they declined to participate during the study.
	Results - Reported participant flow with number of exclusion, randomisation, allocation, follow-up and lost to follow-up and ITT and completers analysis - Also, reported values in mean weight with both SD and SE - Both groups reported statistically significant differences at $p < 0.01$ or 0.001 to strongly significant difference. - At 1 year for ITT analysis, participants' mean weight loss in commercial group (4.3 ± 6.1 kg) was greater than those in self-help group (1.3 ± 6.1 kg) whilst at 2 years, participants' mean weight loss in commercial group (2.9 ± 6.5 kg) was greater than those in self-help group (0.2 ± 6.5 kg) at $p < 0.001$.
	Discussion The authors mainly summarised findings of this study. The commercial weight loss programme had greater weight loss than the self-help group for 2-year programme. Participants attended in the commercial programmes longer than the self-help programme. As a consequence, other outcomes such as weight maintenance, WC, cardiovascular risk factor and biological parameters have been improved.

Heshka 2003 (continued)

Discussions	
Interpretation (continued)	Discussion (continued) Also, they summarised the correlation of changes to additionally analyse factors related, however, it was low correlation and not clearly known for weight loss. Thus, further research would be recommended. Authors also discussed about statistical methods on power calculation to detect differences in weight loss. Moreover, there was no comparing to other studies because this study was a long-term study.
Generalisability	No generalisability because of one particular commercial weight loss programme with many unique aspects but not many commercial programmes
Other evidence	General comments Recommendation for further study: The tendency for successful participants who were more likely to lose weight may not have self-selection bias. However, the length of the treatment and consequence of number of intervention meetings may affect the success of weight loss. Participants' willing and motivation may influence the trial results. For overweight and obese adults, a structured commercial weight loss programme provided moderate weight loss but it was more effective than brief counselling and self-help programme.
Funding	Weight Watchers International

Jebb 2011[152]

Article identification: 2/2011	Reviewer's initials: SS	Verifier's initials: HB
Author and year: Jebb 2011		Country: Australia, Germany, UK
Objectives	Compared weight loss in primary care referral to a commercial weight loss programme with standard care and examined the association of risk factors	
Methods		
Participants	Inclusion criteria: Eligible participants aged at least 18 years, had BMI between 27-35 kg/m^2 who had at least one additional risk factor for obesity-related disease Risk factors included: Central adiposity (waist circumference > 88 cm in women or >102 cm in men), Type 2 diabetes without insulin treatment, family history of diabetes, previous gestational diabetes or impaired glucose tolerance or impaired fasting glycaemia, Mild to moderate dyslipidaemia (defined by national guidelines) or treatment for dyslipidaemia, treatment for hypertension, Polycystic ovarian syndrome or infertility without apparent cause other than weight, or lower-limb osteoarthritis or abdominal hernia	
	Exclusion criteria: People who lost weight 5 kg or more in the previous 3 months, had history of a clinically diagnosed: Eating disorder, received treatment with effects on weight or appetite, gastro intestinal disorders, previous surgical procedure for weight loss or major surgery in the previous 3 months, Orthopaedic limitations preventing participation in regular physical activity, Untreated thyroid disease or more than one change in thyroid treatment in the previous 6 months, insulin-treated diabetes or diabetes diagnosis in the previous 6 months, glycated haemoglobin (HbA_{1C}) of at least 75 mmol/mol (9.0%), Pregnancy or lactation and heart problems in the previous 3 months Uncontrolled hypertension, new prescription drug for a chronic disorder in the previous 3 months or change in dose in the previous 1 month, History or presence of cancer, with the exception of completely resected basal or squamous cell carcinoma if treatment completed 6 months before enrolment, or Participating in another clinical trial in the previous 30 days	
	Settings and/or locations: Primary care practices in Germany, Australia and UK	
	Duration: 12 months, September 10, 2007 to November 28, 2008	
	Recruitment methods: A multicentre, randomised controlled trial with a parallel design. Participants were recruited from 39, 70 and 6 primary care practices in Germany, Australia and UK, respectively	
	Sample size: 772 were eligible participants.	
Study design	Randomisation-sequence generation: Stratification. Data manager generated the randomisation sequence by using computer generated with Stata.	
	Allocation concealment: Allocated in a 1:1 ratio. 772 participants were remained as 268 Germany, 268 Australia and 236 UK, entered the trial and completed a baseline assessment. 377 allocated to commercial programme. 395 allocated to standard care.	
	Implementation: No description	
	Blinding: non-blinded	

Jebb 2011 (continued)

Methods	
Study design (continued)	Statistical methods: For recruitment in 3 countries, power of analysis was 90% at a 5% significance level. For the primary outcome, data analysis included all randomised participants with last observation carried forward (LOCF). Weight change at 12 months used linear regression with fixed effects for continuous normal data, intervention group 9commercial programme vs. standard care), country (Australia, Germany and UK). Values presented as mean ± SE with 95% CI from STATA V11.0.
Intervention	12 months of free membership to a commercial programme (Weight Watchers) and followed-up for other 12 months Meeting weekly for 12 months consisted of weigh-in, group discussion, behavioural counselling and motivation Promoting a hypoenergetic, balanced diet based on healthy-eating principles Increasing exercise and group support Accessing Internet to monitor participants' food intake, activity and weight change, to participate in community discussion boards, and to access a library of information, recipes and meal ideas
Comparison/ Control	Standard care defined by national treatment guidelines: Receiving weight loss advice from a primary care professional
Outcomes	Primary outcome measures: Weight change from baseline to 12 months
Results	
Participant flow	1010 participants were eligible. 238 participants excluded. 772 participants randomised. 377 allocated to commercial programme. 395 allocated to standard care. Commercial programme: 147 participants withdrew. 230 participants completed at 12 months. Standard care: 181 participants withdrew. 214 participants completed at 12 months.

Table 1: Participants' characteristics at baseline, mean (± SD)

	Commercial programme, n = 377	Standard care, n = 395
Sex: Men/Women (%)	47/330 (12/88)	57/338 (14/86)
Age, years	46.5 (13.5)	48.2 (12.2)
Weight, kg	86.9 (11.6)	86.5 (11.5)
BMI, kg/m^2	31.5 (2.6)	31.3 (2.6)

Participants' characteristics in all diet groups were mostly women (87%), aged 47 years with mean weight 86.7 kg and mean BMI 31.4 kg/m^2, approximately.

Number analyzed	ITT: Participants completed the 12-month assessment between baseline and last observation carried forward (BOCF and LOCF). 377 participants in the commercial programme. 395 participants in standard care. At 12 months, 328 (42%) participants from both groups had withdrawn from the trial which were 230 in the commercial programme group and 214 in standard care group to be included in completers-only analysis, respectively.

Jebb 2011 (continued)

Results	
Outcomes and estimation	

Table 2: Weight changes at 12 months by different analysis, mean (± SE)

Body weight, kg	Commercial programme	Standard care	Adjusted difference (95% CI)*	*p*-value
LOCF[a], n = 772	-5.06 (0.31)	-2.25 (0.21)	-2.77 (-3.50 to -2.03)	< 0.0001
BOCF[a], n = 772	-4.06 (0.31)	-1.77 (0.19)	-2.29 (-2.99 to -1.58)	< 0.0001
Completers, n = 444	-6.65 (0.43)	-3.26 (0.33)	-3.16 (-4.23 to -2.11)	< 0.0001

*Adjusted for baseline observation and country

[a]LOCF = Last observation carried forward, BOCF = Baseline observation carried forward

Primary outcome: At 12 months with LOCF, participants' weight change (n = 772) in commercial programme was -5.06 kg (5.8%) whilst standard care was -2.25 kg (2.6%). For BOCF analysis, participants' weight change (n = 772) in commercial programme was -4.06 kg (4.7%) whilst standard care was -1.77 kg (2.0%). Lastly, for completers analysis, participants' weight change (n = 444) in commercial programme was -6.65 kg (7.7%) whilst standard care was -3.26 kg (3.8%). All groups were statistically significant difference at *p*-value < 0.0001.	
Adverse events	No any severe adverse events
Discussions	
Interpretation	Introduction - Reviewed obesity as the worldwide health issue, the proportion of overweight people around the world and health risk factors related to obesity US - Reviewed the relevant studies of commercial weight loss programme - Described the matter of this study: No studies of assessing the effects of commercial weight loss programme compared with standard care in a primary health-care setting - Explained objectives of this study
	Methods A multicentre, randomised controlled trial with a parallel design: Randomisation-sequence was generated by stratification. 772 participants were randomised as 268 in Germany, 268 in Australia and 236 in the UK. 377 and 395 participants were allocated to commercial programme and standard care, respectively. Randomisation was implemented by data manager using computer generated with Stata. Reported blinding as non-blinded Comparison of 2 programmes: Commercial programme and standard care Assessing outcomes: In the UK and Australia, measured weight in the light clothes without shoes with a Tanita BC-418 segmental body composition analyser (Tanita Corporation of America, Arlington Heights, IL, US) In Germany, measured weight in GP practices with standard scales. Weight scale was different from UK and Australia. To present valid values, it should be calibrated weight by repeating and report as the average value. Providers: Primary care provider, a facilitator from ALED and HEED. Statistical methods: Reported power calculation to detect a difference in weight change of 2.6 kg to complete participants in the end of the programme Power calculation could help this study for: 1) Scanning whether or not participants randomised were enough to see an effect, 2) not wasting time on an underpowered study and 3) preparing for sufficient participants if they declined to participate during the study. Also, reported *p*-value, significant level, confidence intervals, tests used and programme analysed

Jebb 2011 (continued)

Discussions	
Interpretation (continued)	Results - Presented participants' flow including eligible, excluded, randomised, allocated, withdrew and completed participants. ITT and completers analysis were reported. - Reported the percentage of completed participants at 12 months: 230 (61%) in commercial programme and 214 (54%) in standard care - Reported values in mean weight with SE and 95% CI - Both programmes reported statistically significant differences ($p < 0.05$). - At 12 months with all 3 analyses, participants' weight change in commercial programme was as twice as those in standard care. Adjusted differences of weight change between groups were -2.77 kg with LOCF, -2.29 kg with BOCF and -3.16 kg with completers. Values of weight change with completers analysis were highest. The authors could only present the most difference of weight change, however, the total number of participants in this analysis was 444 (57%) so that ITT analysis was also reported to compare more weight change in commercial programme with all analyses.
	Discussion The authors summarised findings which were participants in the commercial programme lost 5% or more of the initial weight for 12 months. They also compared this study to other similar studies in other countries and discussed about the risk factors related and setting with primary care providers. Based on other evidences related to standard care, the counterweight programme was compared. There was similar to this study. Likely, commercial programme compared with Jenny Craig and also found that weight change was alike. However, the commercial programme in this study collaborated with primary care providers to offer the effective treatment in a primary care setting. Another factor to support the effective weight loss in standard care was the variables recorded more corresponding than those in commercial programme such as health care setting and systems and motivation from peer-support.
Generalisability	Did not report
Other evidence	General comments Weight change in the commercial programme was as similar as other community-based programme or self-help groups. Although participants participated in a primary care weight loss treatment, primary care providers could offer a commercial programme for options of the effective treatment. Recommendation for further study: Needed to examine long-term weight loss maintenance, analysis of cost-effectiveness and only men Participants who have been selected by a primary health-care professional were transferred from primary care to commercial weight loss programme. They found that commercial programme not only provided regular weighing, advice about diet and exercise, motivation and group support but also offered a clinically useful early intervention for weight management in overweight and obese people at the larger scale.
Funding	Weight Watchers International

Jolly 2011[17]

Article identification: 3/2011	Reviewer's initials: SS	Verifier's initials: HB
Author and year: Jolly 2011		Country: UK
Objectives	Assessed the effectiveness of a range of weight loss programmes on weight loss	
Methods		
Participants	Inclusion criteria: Eligible participants aged ≥ 18 years and had been recorded BMI in their primary care notes in the last 15 months. Categories for invitation to weight loss programmes: - White Europeans and all ethnic groups apart from South Asians with comorbidities, BMI ≥ 28 kg/m^2 or without comorbidities, BMI ≥ 30 kg/m^2 - South Asians with comorbidities, BMI ≥ 23 kg/m^2 or without comorbidities: BMI ≥ 25 kg/m^2	
	Exclusion criteria: Patients were not able to understand English or pregnant.	
	Settings and/or locations: 17 primary care trust in South Birmingham, England	
	Duration: 12 weeks from January to May 2009	
	Recruitment methods: Eligible participants registered with general practices in South Birmingham primary care trust.	
	Sample size: 740 obese or overweight men and women with a comorbid disorder	
Study design	Randomisation-sequence generation: 8-arm randomised controlled trial Block size of 35 from 10 other practices to one of seven study groups excluding GP in the block size of 13. Comparing interventions with a comparator group (Choice of any of the six programmes for the final study arm) One to one randomisation across groups by blocking sizes. Exceptionally, 2 primary care arms were not used blocking and any spaces were limited so that allocation was in a ratio 1 to 0.7 compared with other groups.	
	Allocation concealment: GP, pharmacy or minimal intervention (comparator) groups were allocated by participants at the first sessions. 100 participants were allocated to each arm. Exceptionally, the general practice and pharmacy arms were restricted to 70 participants per arm. An independent statistician generated to allocate separating 2 randomisation sequences, to ensure blinding and the allocation in opaque, and to consecutively number envelopes.	
	Implementation: General practitioners enrolled participants. Nurses assigned participants to interventions and informed them on how to withdraw from the trial if they changed their minds. A trained practice nurse, health trainer or researcher was blinded to the allocation group did the one year assessment at the participant's general practice or home.	
	Blinding: A trained practice nurse, health trainer or researcher blinded.	
	Statistical methods: Used 90% power, significant level at 5% and assume 20% loss to follow-up. Thus, at least 70 participants were randomised to each group. The 2 kg difference was selected to achieve weight loss at 12 weeks and also 5% weight loss was clinically meaningful health benefits. Sample size calculation: No adjustment for multiple comparisons Used Stata v11.0 and SPSS v17.0 for data analysis	

Jolly 2011 (continued)

Methods	
Study design (continued)	Investigating differences between 7-intervention groups and the comparator by measuring outcomes on a continuous scale (weight loss) by using least squares linear regression Bonferroni correction was used to compare as a pair-wise between intervention and control to maintain a 5% type I error across the 7 comparisons.
Intervention 1	Weight Watchers: One to one support Followed by a group talk from the leader with discussion in community venues lasted one hour Delivered core programme material over five weeks included a food points system (based on age, sex, height, weight, and activity), beating hunger, taking more physical activity, eating out, and keeping motivated. Planned aims for 500 kcal (2.09 MJ) deficit/day, leading to 0.5-1.0 kg weight loss a week Encouraged physical activity to gradually build up to 10,000 steps daily Changed behaviour included stages of change, food and activity diaries, goal setting and evaluation of progress Had given rewards for every 3.2 kg (7 lb) lost and for loss of 5% and 10% of body weight
Intervention 2	Slimming World: Setting weight loss goals by the individual, 90 minutes lasted Accessed a website, magazines and one to one telephone support from a consultant or other members Encouraged members to mainly eat foods with low energy density to achieve satiety, plus some extras rich in calcium and fibre with controlled amounts of high energy dense foods Supported physical activity with gradual build up to 30 minutes of moderately intense activity five days a week Group supported Rewarded for 3.2 kg (7 lbs) lost and loss of 10% of body weight Individual supported, if needed such as self monitoring of food and emotions, visualisation techniques and personal eating plans
Intervention 3	Rosemary Conley: One to one support, 90 minute lasted Available supported by email and telephone Set goals: either 1-1.5 kg/week with a goal of 6.35 kg (1 stone) loss or 0.5-1 kg/week with an initial goal of 3.2 kg (7 lb) Optional exercise class for 45 minutes. Offered extra exercise sessions for an additional fee. Role modelling and group supporting Rewarded for slimmers who maintain or lose weight, slimmer of the week, and certificates for 3.2 kg and 6.35kg milestones
Intervention 4	Dietetics led programme: The Size Down Programme - An NHS group based programme run in the community Supported workers trained by the dietetics service Provided 6 weekly 2 hour sessions, with follow-up sessions at 9 and 12 weeks to focus on long term changes in patterns of eating behaviour, achieving a balanced diet and increasing physical activity in daily life with an interactive style Managed behaviour around food and prevention of relapse, the eat well plate, nutritional information, planning strategies to deal with lapses into previous dietary behaviours, interactive visual aids to show the fat and sugar content of foods and adaptation of recipes Based on the cycle of change as a theoretical background Discussed about the benefits of physical activity, setting goals and finding activities to fit into life which included goal setting, stages of change and self monitoring with a food diary

Jolly 2011 (continued)

Methods	
Intervention 5 and 6	General practice and pharmacy led: One to one counselling Lasted 30 minutes with follow-up sessions of 15-20 minutes Solved problems approach which included weight and dieting history Explored goals and expectations of patients, the eat well plate, setting goals to reduce calorie intake and increase physical activity, planning strategies to deal with challenging situations, use of food diaries, and maintaining weight loss Weight loss goals were 5-10% of the initial body weight, at a rate of 0.5-1 kg/week over three to six months with following by weight maintenance Increased physical activity goals to slowly achieve 30 minutes of moderate activity on five days a week Self monitored with food diaries, hunger scale, waist measurements and physical activity Provided resources as homework for discussion in the next session or for personal reflection. Motivated to reward patients for success
Intervention 7	Choice of any of the six programmes
Comparison/ Control	The comparator group (Exercise): Provided 12 vouchers to enabling free entrance to a local leisure (fitness) centre where consisted of a swimming pool, fitness suite and other sport halls or courts Had no appointment and individual advice and support on diet or exercise
Outcomes	Primary outcome measure: Weight loss Secondary outcome measure: Weight loss at 1 year and percentage weight loss at 12 weeks and 1 year. Results also presented effects of choice and sex, physical activity, attendance and costs but not extracted here.
Results	
Participant flow	8810 people received the invitation letters. 7799 did not respond. 740 participants were randomised. 271 participated in Lighten Up services as a part of pilot study. 100 participants each were assigned to Weight Watchers, Slimming World, Rosemary Conley, NHS Size Down, Choice and comparator. 70 participants each were assigned to general practice and pharmacy.
Baseline data	

Table 1: Participants' characteristics, mean (± SD)

	1[a]	2[b]	3[c]	4[d]	5[e]	6[f]	7[g]	8[h]
Male sex, %	28	35	31	36	33	27	30	25
Age, years	50.7 (14.6)	48.8 (14.9)	49.8 (14.5)	48.7 (15.6)	50.5 (13.8)	48.9 (15.8)	47.4 (14.4)	49.7 (13.8)
Weight, kg	93.5 (14.2)	94.4 (13.4)	93.7 (13.7)	95.5 (17.9)	92.0 (14.8)	92.8 (13.7)	91.7 (12.5)	93.1 (15.1)
BMI, kg/m^2	34.0 (3.9)	33.8 (3.8)	33.4 (3.5)	33.8 (3.9)	33.1 (3.5)	33.4 (3.5)	33.4 (3.5)	33.9 (4.4)

[a]1 = Weight Watchers, [b]2 = Slimming World, [c]3 = Rosemary Conley, [d]4 = Size down, [e]5 = General Practice, [f]6 = Pharmacy, [g]7 = Choice, [h]8 = Comparator/Exercise

Jolly 2011 (continued)

Results	
Baseline data (continued)	Participants' characteristics in all groups were mainly female (70%) and aged 49.3 years with mean weight 93.3 kg and mean BMI 33.6 kg/m^2, approximately.
Number analyzed	ITT: 100 participants of each group for Weight Watchers, Slimming World, Rosemary Conley, Size Down, Choice and Comparator 70 participants of each group for general practice and pharmacy
Outcomes and estimation	

Table 2: Weight loss (kg) between CWLPs and comparator group at 12 weeks

kg	1[a]	2[b]	3[c]	4[d]	5[e]	6[f]	7[g]	8[h]
WL	4.4 (3.6-5.3)[*]	3.6 (2.7-4.4)[*]	4.2 (3.2-5.2)[*]	2.4 (1.7-3.1)[*]	1.4 (0.4-2.3)[**]	2.1 (1.0-3.2)[*]	3.3 (2.5-4.1)[*]	2.0 (1.2-2.8)[*]

[a]1 = Weight Watchers, [b]2 = Slimming World, [c]3 = Rosemary Conley, [d]4 = Size down, [e]5 = General Practice, [f]6 = Pharmacy, [g]7 = Choice, [h]8 = Comparator/Exercise, [*]$p \leq 0.001$, [**]$p < 0.05$

WL = Weight loss

At 12 weeks, participants' mean weight loss in Weight Watchers (4.4 kg, 4.7%) was greater than other groups as Rosemary Conley (4.2 kg, 4.5%), Slimming World (3.6 kg, 3.8%), Choice (3.3 kg, 3.6 %), Size down (2.4 kg, 2.5%), Pharmacy (2.1 kg, 2.3%), Comparator (2.0 kg, 2.1%) and general practice (1.4 kg, 1.5%), respectively. There were statistically significant differences between commercial weight loss programmes and comparator group ($p \leq 0.001$).

Table 3: Differences of weight loss (kg and percentage) between CWLPs and comparator group and proportion of each CWLP at one year (exercise only)

CWLPs[a]	Mean different weight loss in kg (95% CI)[b]	*p*-value[c]	Mean different weight loss in percentage (95% CI)	*p*-value[c]	Proportion of achieving 5% weight loss (95% CI)
WW[d]	-2.4 (-3.6 to -1.2)	< 0.001	-2.5 (-3.8 to -1.3)	< 0.001	46.0 (36.0 to 56.3)
SW[e]	-1.5 (-2.7 to -0.4)	0.072	-1.5 (-2.7 to -0.3)	0.106	35.0 (25.7 to 45.2)
RC[f]	-2.2 (-3.4 to -1.0)	0.001	-2.2 (-3.4 to -1.0)	0.004	42.0 (32.2 to 52.3)

[a]CWLPs = Commercial Weight loss Programmes, [b]95%CI = 95% Confident Interval, [c]*p*-value < 0.05 considered statistically significant, [d]WW = Weight Watchers, [e]SW = Slimming World, [f]RC = Rosemary Conley

The differences of mean weight loss between commercial weight loss programmes and comparator groups were statistically significant difference in Weight Watchers (2.4 kg, 2.5%, $p < 0.001$) and Rosemary Conley (2.2 kg, 2.2%, $p < 0.05$). Consequently, commercial weight loss programmes were more likely effective than comparators, especially Weight Watchers was the most success of weight loss.

Adverse events	Did not report
Discussions	
Interpretation	Introduction - Reviewed increasing in the global epidemic obesity worldwide from WHO, the definition of obesity by WHO, BMI range, the percentage of obesity and broadly weight loss programme participated in England, guideline for primary care physicians and NHS for obese patients - Reviewed the relevant studies in the US and found that there were good evidences in comparing between commercial weight loss and primary care programmes - Addressed the study type in the previous research such as the Counterweight programme used a cluster randomised trial - Described the matter of this study: Lack of evidences in the effectiveness of obesity management in primary care and explained objectives of this study

Jolly 2011 (continued)

Discussions	
Interpretation (continued)	Methods 8-arm randomised controlled trial: Randomisation-sequence was generated by using block size of 35 from 10 other practices to one of seven study groups excluding GP in the block size of 13. Comparing interventions with a comparator group (Choice of any of the six programmes for the final study arm) One to one randomisation across groups by blocking sizes. Two primary care arms were not used blocking so that allocation was in a ratio 1 to 0.7 compared with other groups. For GP, pharmacy or minimal intervention (comparator) groups were allocated by participants at the first sessions. 100 participants were allocated to each arm. There were only the GP and pharmacy arms restricted to 70 participants per arm. An independent statistician implemented randomisation sequences and ensured blinding and the allocation in opaque and the consecutively number envelopes. A trained practice nurse, health trainer or researcher was blinded to the allocation group did the one year assessment at the participant's general practice or home. A trained practice nurse, health trainer or researcher was blinded. Blinding was only investigator side that meant single blind. Participants were not blinded because they need to know what programme structures were and how they were consulted. Comparison of 8 arms: 1) Weight Watchers, 2) Slimming World, 3) Rosemary Conley, 4) Size Down, 5) General practice, 6) Pharmacy, 7) Choice and 8) Exercise/comparator Assessing outcomes: Measured weight without shoes in light clothing, and height was measured by using a Seca Leicester portable height. However, some CWLP collected height and weight self-reported. Participants could inform their higher height and lower weight to a researcher. As a result, average height and weight in such groups would not naturally differ from the measuring groups. Provider: General practitioner, nurse, food advisor Statistical methods: Reported power calculation, *p*-value, tests used, programme analysed, confidence intervals. There were BOCF, LOCF and completers analysis, however BOCF was only primary analysis. Power calculation was for: 1) Detecting sample size for the sufficient participants randomised to see an effect and 2) preparing for sufficient participants if they declined to participate during the study.
	Results - Presented participants' flow, number of no response, exclusion and follow-up - Reported values in mean weight with both SD and SE including 95% CI - All 8 arms reported statistically significant differences within groups. - At 1 year, participants' mean weight loss in Weight Watchers (4.4 kg) was greater than Pharmacy (2.1 kg), Comparator (2.0 kg) and general practice (1.4 kg), respectively. There were statistically significant differences between Weight Watchers and comparator group (2.5 kg, 95% CI: 0.8 to 4.2).
	Discussion The authors summarised the primary outcome of successful weight loss and mentioned that Weight Watchers and Rosemary Conley had significantly higher weight loss than those in the comparator. They also discussed about details of interventions such as physical activity. Based on other previous evidences of commercial weight loss programme, the outcome of this study was compared to studies of Jebb, Truby and Hardcastle. In contrast, the Counterweight Project Team was used to compare with the rest of weight loss programmes.

Jolly 2011 (continued)

Discussions	
Interpretation (continued)	Discussion (continued) Factors related to lower weight loss in GP or pharmacy were discussed as training counsellors, group support, participants' feedback about the convenience of programme or setting, primary care practitioner's ability (knowledge and practice), health conditions such as smoking and behavioural change. Other influences could be from participants' characteristics such as gender (more women), ethnicity (majority) and socioeconomic deprivation. Strengths: Robust evaluation of commercial weight loss services, more diverse of ethnic groups and people's willing to afford to participate the programme Limitations: 1) Measuring weight by self-reporting may be overestimate, 2) Low response rate to the invitation (11.5%), 3) Only people who had willingness to purchase the commercial programmes and 4) Group leaders might practice to have good skills to encourage other participants in losing weight. Further study: Explore factors influenced Weight Watchers with the highest weight change of commercial weight loss programmes
Generalisability	Applicable for CWLP such as Weight Watchers, Slimming World and Rosemary Conley
Other evidence	General comments Non-pharmacological weight loss programme using diet and physical activity in the programme Comparison among commercial weight loss programmes and other weight loss programmes in different setting areas has been found that 3 CWLPs were more effective than primary care based services. Comparison of weight loss among 3 CWLPs was similar in terms of Weight Watchers and Rosemary Conley but less weight loss in Slimming World.
Funding	NHS South Birmingham

Luszczynska 2007[156]

Article identification: 4/2007	Reviewer's initials: SS	Verifier's initials: HB
Author and year: Luszczynska 2007		Country: UK, Poland
Objectives	Investigated the effects of the implementation intention prompt (IIP) on weight reduction	
Methods		
Participants	Inclusion criteria: Overweight or obese women aged 18-76 years with BMI > 25 kg/m^2.	
	Exclusion criteria: Participants had BMI ≤ 25 kg/m^2.	
	Settings and/or locations: Warsaw, Poland	
	Duration: 2 months	
	Recruitment methods: Recruited participants from Weight Watchers programme	
	Sample size: 55 participants randomised	
Study design	Randomisation-sequence generation: Randomised controlled trial Sequence began with the first person with BMI > 25 kg/m^2 No blocking and stratification. Randomised by a random digit generator	
	Allocation concealment: No description. 28 and 27 participants in the control and the IIP condition, respectively 2 and 3 participants from the control and the experimental groups were not available for follow-up. Thus, the final samples were 25 each from both groups.	
	Implementation: No description	
	Blinding: Experimenters	
	Statistical methods: Used ANOVA to measure weight, BMI and frequency of planning	
Intervention	Weight Watchers with IIP: Participants were - Invited to make a plan about their diet and exercise - Planned by writing details in 6 food categories such as sweets, fat food, vegetables, fruits, meat and whole grain products - Provided a plan about how you would react to the risky situations and fill in the form - Recorded their exercise plan If a researcher checked about participants' plan and found that it was occasion to do so, they should consider and review their plan to completely encourage the regular plan.	
Control	The standard Weight Watchers programme provided weekly as: - 1-hour group meeting for 7-12 participants focusing on nutrition, exercise, behavioural weight control strategies and social support by group members.	
Outcomes	Primary outcome measures: Change in weight and BMI	

Luszczynska 2007 (continued)

Results	
Participant flow	Did not report

Baseline data, outcomes and estimation

Table 1: Participants' body weight and BMI at baseline and 2 months, mean (± SD)

	Control group		IIP group	
	Baseline	2 months	Baseline	2 months
Body weight, kg	89.43 (19.41)	87.33 (21.15)	88.61 (21.88)	84.48 (19.48)
BMI, kg/m^2	33.41 (6.48)	32.88 (6.02)	32.98 (6.66)	31.07 (6.25)

At 2 months, participants in the IIP group (4.2 kg, 4.7%) were greater weight loss than those in control group (2.1 kg, 2.4%) as well as their BMI in the IIP group (1.91 kg/m^2) and the control group (0.53 kg/m^2).

Number analyzed	ITT: Did not report
Adverse events	Did not report
Discussions	
Interpretation	Introduction - Reviewed overweight and obesity as risk factors for chronic disease, increasing in obesity in 4 continentals such as North America; Europe; Asia and Australia since 1980s, weight loss approaches such as diet modification; increasing exercise and cognitive behaviour change strategies - Reviewed the relevant studies about the commercial weight loss programme, especially Weight Watchers including benefits from the programme - Also, reviewed about theory used in this study, implementation, intentions, planning and behaviour change, studies supported this theory - Described the matter of this study: Focused on overweight and obese women in Weight Watchers - Hypothesis was 1) Participants receiving the implementation intention prompt (IIP) should lose more weight and achieve a lower BMI than those in the standard Weight Watchers for 2 months, 2) Participants receiving the IIP should report more frequent action planning and 3) reported frequency of action planning should mediate the effects of the IIP on weight and BMI. - Explained objectives of this study
	Methods Randomised controlled trial: Randomisation-sequence was begun with the first person with BMI > 25 kg/m^2. No blocking and stratification 28 and 27 participants were allocated to the control and the IIP condition, respectively. Implemented randomisation by a random digit generator Participants (Experimenters) were blinded. Comparison of 2 programmes: Control (Standard Weight Watchers) and IIP groups Assessing outcomes: Measured weight by an experimenter to avoid self-reporting bias. Weight value should be valid. Provider: Only group supporters Statistical methods: No report of level of significant difference, power analysis and programmed used. There was no power calculation in this study to 1) Detect a difference between baseline and the end of treatment with both groups, 2) scan whether or not participants randomised were enough to see an effect, 3) not waste time on an underpowered study and 4) prepare for sufficient participants if they declined to participate during the study.

Luszczynska 2007 (continued)

Discussions	
Interpretation (continued)	Results - No report of participants' flow and either ITT or completers analysis - Reported values in mean weight with SD and presented weight change in graph - Both programmes reported statistically significant differences at $p < 0.05$. - At 2 months, participants in the IIP group (4.1 kg, 95% CI: 3.19 to 5.07) were greater weight loss than those in control group (2.1 kg, 95% CI: 1.11 to 3.09) as well as their BMI in the IIP group (1.91 kg/m^2) and the control group (0.53 kg/m^2). The change in frequent action planning mediated the effects of the IIP on weight loss and BMI.
	Discussion The authors summarised the findings and compared to the similar studies such as study of Heshka. They also discussed about the percentage of interventions effects in clinical outcome and other variables related. However, this study was claimed that results supported the previous research in terms of IIP and also described how IIP was successful and inexpensive to people who prefer to change their behaviour.
Generalisability	Did not report
Other evidence	General comments Limitations: Small sample size Further study: Assess for - Generalisability to other weight loss programmes including community-based programmes - The record of action plans weekly as well as self-reporting planning and measuring lifestyle change - Overweight and obese men - Larger sample size if possible
Funding	Warsaw University

Rock 2007[153]

Article identification: 5/2007	Reviewer's initials: SS	Verifier's initials: HB
Author and year: Rock 2007		Country: US
Objectives	Tested whether a multifaceted commercial weight loss programme (Jenny Craig, JC) promotes greater weight loss in overweight or obese women compared with control conditions	
Methods		
Participants	Inclusion criteria: Overweight or obese women in San Diego who aged 18 years and older with BMI 25-40 kg/m^2 were willing and able to participate in clinic visits and maintained to contact investigators for 2 years.	
	Exclusion criteria: Participants were - Unable to exercise because of severe disability such as severe arthritic conditions - Reported a history of presence of a comorbid disease, currently pregnant, breastfeeding or plan a pregnancy in the next 2 years	
	Settings and/or locations: San Diego	
	Duration: 12 months	
	Recruitment methods: 276 women screened by telephone as a part of interview	
	Sample size: 70 women randomised	
Study design	Randomisation-sequence generation: Randomised trial Participants were stratified by BMI 25-29.9 vs. ≥ 30 kg/m^2 and age ≤ 40 and ≥ 40 years and randomised to 1 of the 2 study groups. 276 women screened. 98 women met the inclusion criteria to invite to a clinic visit. 28 women were ineligible whilst 70 women were enrolled in the study.	
	Allocation concealment: Insufficient information. 35 women each were in usual care control group and JC intervention	
	Implementation: Did not report	
	Blinding: Did not report	
	Statistical methods: Baseline data used 2-sample t tests for continuous variables or χ^2 tests for categorical variables and paired t tests for within-group changes for primary analysis. 2-sample t test was used to compare changes in weight and BMI between both groups at 6 and 12 months. Weight change at least 5% of the initial weight was examined weight loss from baseline to 6 and 12 months by using SAS V9.1.	
Both groups	At baseline, 6 and 12 months visits, all participants were examined their step test.	
Intervention	Commercial weight loss programme (JC): Participants received - All programme materials including prepackaged prepared foods - Description of addressing food, body and mind - Weekly one-to-one contact with a consultant with follow-up telephone, e-mail contact and website or message board The prepackaged prepared foods included: - Vegetables, fruit and other additional strategies, provided weekly interactions at a community-based facility. - The average energy contribution was 820 kcal per day or energy intake 1200-2300 kcal per day (35%-68% of clients' energy) Increasing physical activity consisted of goal setting, exercise half an hour on 5 or more days/week.	

Rock 2007 (continued)

Methods	
Comparison/ Control	Usual care control group - Non-prepackaged foods included meals, snacks, vegetables, fruit and dairy products - Consultation at baseline and 16 weeks with a research staff dietician - Weight loss achieved at least 10% over 6 months - Specific meal plans and recommendations to increase exercise were provided to individual participants.
Outcomes	Primary outcome measures: Weight loss
Results	
Participant flow	276 women screened by telephone. 178 were ineligible. 98 screened at the clinic visit. 28 were ineligible. 70 women randomised. 35 women each in usual care control group and JC intervention At 12 months, 32 participants in intervention group and 33 participants in usual care control group
Baseline data	Table 1: Participants' characteristics at baseline, n = 35 each and mean (± SD)

	Intervention group	Usual care control group
Age, years	42 (11)	40 (12)
BMI, kg/m^2	34.2 (3.7)	33.8 (3.4)
Weight, kg	94.4 (12.2)	89.6 (9.4)

Participants' characteristics in both groups aged 41 (11.4) years, had mean BMI 34 (3.5) kg/m^2 and mean weight 92 (11.1) kg.

Number analyzed	ITT: 35 participants each in intervention group and usual care control group Completers: At 12 months, 32 participants in intervention group and 33 participants in usual care control group

Outcomes and estimation

Table 2: Weight and BMI changes from baseline to 6 and 12 months by ITT and completers, mean (± SD)

	Intervention group			Usual care control group		
	6 mo, ITT	12 mo, ITT	12 mo, completers*	6 mo, ITT	12 mo, ITT	12 mo, completers*
Weight change, kg**	-7.2 (6.7)	-6.6 (10.2)	-7.3 (10.4)	-0.3 (3.9)	-0.7 (5.5)	-0.7 (5.6)
% Weight change**	-7.8 (7.2)	-7.1 (10.8)	-7.8 (11.1)	-0.3 (4.5)	-0.7 (6.0)	-0.7 (6.2)
BMI change, kg/m^{2}**	-2.6 (2.5)	-2.4 (3.8)	-2.6 (3.9)	-0.2 (1.5)	-0.3 (2.1)	-0.3 (2.1)

*At 12 months, 32 participants in intervention group and 33 participants in usual care control group

**Significant at $p < 0.01$ between groups at 6 and 12 months

At 6 months, mean weight change of participants by ITT (87.2 kg, 7.8%) in the intervention group were greater mean weight than those in the usual care control group (89.3 kg, 0.3%) as well as BMI in the intervention group (31.6 kg/m^2) and the usual care control group (33.6 kg/m^2), respectively.

Rock 2007 (continued)

Outcomes and estimation (continued)	
At 12 months, mean weight change of participants by completers (87.1 kg, 7.8%) in the intervention group were greater mean weight than those in the usual care control group (88.9 kg, 0.7%) as well as BMI in the intervention group (31.6 kg/m^2) and the usual care control group (33.5 kg/m^2), respectively.	
Adverse events	Did not report
Discussions	
Interpretation	Introduction - Reviewed the prevalence of obese US adults increased over 20 years, BMI range of overweight and obesity and health risk factors related - Reviewed the relevant studies tested weight loss strategies and interventions and the previous research of Metz; Jenny Craig programme and Heshka - Also, reviewed energy intake and expenditure including energy density to know how they manipulate on weight loss - Described the matter of this study: No studies of a multifaceted commercial weight loss programme tested in a randomised trial - Explained 2 aims of this study, however, reviewer emphasized only on the first aim to promote weight loss
	Methods Randomised trial: Randomisation sequence was generated by stratification on BMI 25-29.9 vs. ≥ 30 kg/m^2 and age ≤ 40 and ≥ 40 years. Participants were randomly allocated to 1 of the 2 study groups. 70 women were enrolled in the study. 35 women each were in usual care control group and JC intervention. Implementation and blinding were not applicable. Comparison of 2 diets: Usual care control group and JC intervention. At baseline, no statistically significant differences. Assessing outcomes: No description of measuring weight. Both weight and height values could be bias because of over or under estimation. Provider: Dietician Statistical methods: Reported *p*-value, tests used and programme analysed, however, power calculation and confidence intervals were unavailable. There was no power calculation could help this study for: 1) Detecting a difference between treatment programmes in order to scan whether or not participants randomised were enough to see an effect and 2) preparing for sufficient participants if they declined to participate during the study.
	Results - Reported participants' flow, number of eligible participants, screening at clinic visit, randomisation, allocation, exclusion and completers - Also, reported values in mean weight with SD - Both diet groups reported statistically significant differences between groups at $p < 0.05$ and between groups at 6 and 12 month at $p < 0.01$. At baseline, there was no significant difference between groups. At 6 months, mean weight change of participants by ITT (7.2 kg, 7.8%) in the intervention group were greater mean weight than those in the usual care control group (0.3 kg, 0.3%). At 12 months, mean weight change of participants by ITT (6.6 kg, 7.1%) in the intervention group were greater mean weight than those in the usual care control group (0.7 kg, 0.7%).

Rock 2007 (continued)

Discussions	
Interpretation (continued)	Discussion The authors summarised findings and referred to rationale of this study that was the multifaceted approach never tested in a randomised trial. Authors compared to the previous research of Tsai and Wadden that demonstrated the similar results. Based on other evidences, they discussed about the prepackaged meals and snacks and also compared findings to the current study on weight loss and maintenance. Moreover, details on discussion were focused on the main expression of dietary guidance in Jenny Craig and changes of many factors associated with obesity. The authors discussed comparing between commercial programme and control group and lastly concluded by following 2 aims of this study.
Generalisability	Not be able to generalise to all overweight or obese women because the sample only agreed to participate in a RCT.
Other evidence	General comments Limitations: Small sample size, no power calculation and cost-effectiveness If there was power calculation, it would help this study to detect a difference weight loss between groups, to scan whether or not enough participants randomised in order to see an effect and to prepare for sufficient participants if they declined to participate during the study.
Funding	Jenny Craig, Inc

Rock 2010[154]

Article identification: 1/2010	Reviewer's initials: SS	Verifier's initials: HB
Author and year: Rock 2010		Country: US
Objectives	Tested whether a free prepared meal and incentivised structured weight loss programme as centre-based or telephone-based intervention promotes greater weight loss and weight loss maintenance at 2 years in overweight and obese women compared with usual care	
Methods		
Participants	Inclusion criteria: Participants - Aged 18 years or older with BMI of 25 to 40 kg/m^2 - Had a minimum of 15 kg over ideal weight as defined by the 1983 Metropolitan Life Insurance tables - Were willing to participate in any of the 3 study groups over a 2-year period and perform a simple step test for assessing cardiopulmonary fitness - Had no pregnant, breastfeeding or planning to become pregnant in the next 2 years, eating disorders, food allergies or intolerances	
	Exclusion criteria: Women - Had BMI > 40 kg/m^2 because of extreme obesity relating to more serious comorbid conditions - Involved another diet intervention - Were having a history or presence of a significant psychiatric disorder or any other disqualified women There were no men because of the minority of enrolees.	
	Settings and/or locations: US institutions at 4 study sites that consisted of 3 universities as University of California, Arizona, and Minnesota and one centre of health research, Oregon	
	Duration: 24 months	
	Recruitment methods: Recruited participants by using list serves and flyers from the research staff at each site	
	Sample size: 446 participants randomised.	
Study design	Randomisation-sequence generation: Randomised controlled trial No further description	
	Allocation concealment: A 3:3:2 allocation to the centre-based intervention, telephone-based intervention or usual care used to assign for participants each group. 564 women were eligible. 446 participants randomised. Participants were assigned 169 to centre-based intervention, 164 to telephone-based intervention and 113 to the usual care group.	
	Implementation: The study statistician generated a randomisation sequence.	
	Blinding: No blinding for counsellors because of providing the programme instruction	
	Statistical methods: At least 80% power calculation was used. ITT and completers analysis were presented. Values presented as mean (± SD or 95% CI). Data analysis used SAS V9.2 with statistical significance at a 2-sided, $p < 0.05$.	

Rock 2010 (continued)

Methods	
Intervention	A free prepared meal and incentivised weight loss programme Prepared foods and counsellors were provided by Jenny Craig Inc (California). Assigned participants to the centre-based or telephone-based study groups in order to receive all programme materials as free-of-charge pre-packaged prepared foods Briefed participants weekly one-to-one contacts with an in-person or telephone counsellor and follow-up with telephone, e-mail contacts, Web site or message Instructed by counsellors to design same as a regular paying client Diet component: Low-fat (20%-30% of energy) and reduced energy diet (1200-2000 kcal/d) including pre-packaged prepared food items that increased amounts of vegetables and fruits to reduce the energy density of the diet Selected regular foods (e.g. vegetables, fruit, cereal or grain products, low-fat dairy products, lean meat or the equivalent and unsaturated fat sources) when preferred and encouraged participants to follow a menu plan with pre-packaged foods Physical activity: Increased 30 minutes on 5 or more days per week, supported by CDs, DVDs and online tools to increase exercise Stated their attitudes about weight, food and physical activity including recipes and guidance for eating in restaurants
Comparison/ Control	Usual care: Provided consultation by a research staff dietetics professional, dietary material physical activity guidelines to promote weight loss and maintenance at baseline and at 6 months Achieved a weight loss of 10% over a 6-month period by aiming energy intake level of 500 to 1000 kcal/d Planned meal based on food groups Increased physical activity and strategies and skills e.g. reading food labels, estimating serving sizes or eating outside the home Followed by monthly check-in via e-mail or telephone lasted one hour Discussed in a follow-up counselling session at 6 months
Outcomes	Primary outcome measures: Weight loss, weight loss maintenance
Results	
Participant flow	564 women were eligible. 118 participants excluded. 446 participants randomised. 169 participants were assigned to centre-based intervention, 164 participants were assigned to telephone-based intervention and 113 participants were assigned to the usual care group. Centre-based intervention: 164 (5 excluded), 159 (10 excluded) and 151 (18 excluded) participants at 6, 12 and 24 months, respectively Telephone-based intervention: 162 (2 excluded), 157 (7 excluded) and 153 (11 excluded) participants at 6, 12 and 24 months, respectively Usual care group: 103 (10 excluded), 101 (12 excluded) and 103 (10 excluded) participants at 6, 12 and 24 months, respectively Primary analysis: 167 participants in centre-based intervention, 164 participants in telephone-based intervention and 111 participants in usual care group

Rock 2010 (continued)

Results			
Baseline data	Demographic data included age and anthropometric data such as weight and BMI		
Table 1: Demographic characteristics and anthropometric data* of participants at baseline, mean (± SD)			
	Centre-based intervention, n = 167	Telephone-based intervention, n = 164	Usual care, n = 111
Age, year	44 (10)	44 (10)	45 (11)
Weight, kg	92.2 (90.7 to 93.7)	92.9 (91.1 to 94.7)	91.0 (89.0 to 92.9)
BMI, kg/m^2	33.8 (33.3 to 33.4)	33.8 (33.3 to 34.3)	34.0 (33.4 to 34.6)
*Baseline values in anthropometric data were shown in mean (95% confidence interval)			
Participants' characteristics in all 3 groups aged about 44.3 years and had mean weight 92 kg and mean BMI 33.9 kg/m^2, approximately.			
Number analyzed	ITT: 167 participants in centre-based intervention, 164 participants in telephone-based intervention and 111 participants in usual care group Completers: 151 participants in centre-based intervention, 153 participants in telephone-based intervention and 103 participants in usual care group		
Outcomes and estimation			
Table 2: Weight loss by ITT analysis at 6, 12 and 24 months, mean (95% confidence interval)			
	Intention-to-treat analysis, n = 407		
	6 months	12 months	24 months
	Centre-based intervention, n = 167		
Weight, kg	83.0 (81.4 to 84.5)	82.1 (81.3 to 84.6)	84.8 (83.0 to 86.5)
Weight change, kg	-9.2 (-9.9 to -8.4)	-10.1 (-11.2 to -9.0)	-7.4 (-8.7 to -6.1)
BMI, kg/m^2	30.5 (29.9 to 31.0)	30.2 (29.6 to 30.8)	31.2 (30.5 to 31.8)
	Telephone-based intervention, n = 164		
Weight, kg	84.6 (82.8 to 86.4)	84.4 (82.3 to 86.5)	86.6 (84.4 to 88.9)
Weight change, kg	-8.3 (-9.1 to -7.5)	-8.5 (-9.7 to -7.2)	-6.2 (-7.6 to -4.9)
BMI, kg/m^2	30.8 (30.3 to 31.4)	30.7 (30.1 to 31.4)	31.5 (30.4 to 32.2)
	Usual care, n = 111		
Weight, kg	88.1 (86.0 to 90.2)	88.5 (86.3 to 90.8)	89.0 (86.7 to 91.3)
Weight change, kg	-2.9 (-3.8 to -2.0)	-2.4 (-3.6 to -1.2)	-2.0 (-3.3 to -0.6)
BMI, kg/m^2	32.9 (32.2 to 33.6)	33.2 (32.4 to 33.9)	33.4 (32.5 to 34.2)

Rock 2010 (continued)

Results	
Outcomes and estimation	

At 24 months for ITT analysis, participants' mean weight loss in the centre-based group (7.4 kg, 7.9%) and in the telephone-based group (6.2 kg, 6.8%) were greater than those in the usual care control group (2.0 kg, 2.1%).

Table 3: Weight loss by completers analysis at 6, 12 and 24 months, mean (95% confidence interval)

	Completers analysis, n = 442		
	6 months	12 months	24 months
Centre-based intervention	n = 164	n = 159	n = 151
Weight, kg	82.8 (81.3 to 84.4)	81.5 (79.8 to 83.2)	83.8 (82.0 to 85.7)
Weight change, kg	-9.4 (-10.1 to -8.6)	-10.6 (-11.7 to -9.5)	-8.2 (-9.5 to -6.8)
BMI, kg/m^2	30.4 (29.9 to 31.0)	30.0 (29.4 to 30.7)	30.8 (30.2 to 31.5)
Telephone-based intervention	n = 162	n = 157	n = 153
Weight, kg	84.5 (82.7 to 86.3)	83.8 (81.7 to 85.9)	86.1 (83.8 to 88.4)
Weight change, kg	-8.4 (-9.2 to -7.6)	-8.9 (-10.1 to -7.6)	-6.7 (-8.2 to -5.2)
BMI, kg/m^2	30.8 (30.2 to 31.4)	30.5 (29.8 to 31.2)	31.3 (30.6 to 32.0)
Usual care	n = 103	n = 101	n = 103
Weight, kg	87.4 (85.3 to 89.6)	87.7 (85.4 to 90.0)	87.8 (86.3 to 91.1)
Weight change, kg	-3.1 (-4.1 to -2.2)	-2.7 (-3.9 to -1.4)	-2.1 (-3.6 to -0.7)
BMI, kg/m^2	32.7 (33.2 to 34.7)	32.9 (32.1 to 33.7)	33.0 (32.5 to 34.2)

At 12 months for completers analysis, participants' mean weight loss in the centre-based group (8.2 kg, 8.9%) and in the telephone-based group (6.7 kg, 7.2%) were greater than those in the usual care control group (2.1 kg, 2.3%).

Weight loss among 3 groups at 12 months was statistically significant difference ($p < 0.05$). This study showed that the centre-based and telephone-based groups were higher weight loss than the usual care control group. Thus, a free prepared meal and incentivised weight loss programme recommended to control weight for over 2-year period.

Adverse events	Did not report
Discussions	
Interpretation	Introduction - Reviewed the prevalence of overweight and obese US adults, National survey data indicated BMI range of overweight and obesity, health risk factors related to obesity and recommendation from clinical and public health guideline - Described the matter of this study: A few studies of some potential programmes to promote weight loss equal or surpass office-based counselling or medical interventions. - Explained 2 aims of this study, however, reviewer emphasized only on the first aim to promote greater weight loss

Rock 2010 (continued)

Discussions	
Interpretation (continued)	Methods Randomised controlled trial: Randomisation sequence was generated by a ratio of 3:3:2 allocation to the centre-based intervention, telephone-based intervention or usual care used to assign for participants each group. 446 participants were randomly allocated 169 to centre-based intervention, 164 to telephone-based intervention and 113 to the usual care group. Statistician implemented randomisation. No blinding for counsellors because they needed to provide the programme instruction. Comparison of 3 groups: Usual care, the centre-based intervention and telephone-based interventions. At baseline, no statistically significant differences. Assessing outcomes: No description of measuring weight. Both weight and height values could be bias because of over or under estimation. Provider: Dietician Statistical methods: Reported power calculation, *p*-value, values presented with 95% CI, ITT and completers analysis and programme analysed. No report of tests' details. Rock's previous study in 2007 reported about using test as 1) Baseline data used 2-sample t tests for continuous variables or χ^2 tests for categorical variables, 2) 2-sample t test was used to compare changes in weight and BMI between both groups at 6 and 12 months.
	Results - Reported participants' flow, number of exclusion, randomisation, allocation, ITT and completers, and also presented values in mean weight with 95% CI. All groups reported statistically significant differences at $p < 0.05$. At 12 months for ITT analysis with baseline value substitution, participants' mean weight loss in the centre-based group 7.4 kg, (95%CI: 6.1-8.7 kg) or 7.9% (98% CI: 6.5-9.3%) and in the telephone-based group 6.2 kg (95% CI: 4.9-7.6 kg) or 6.8% (95% CI: 5.2-8.4%) were greater than those in the usual care control group 2.0 kg (95% CI: 0.6-3.3 kg) or 2.1% (95% CI: 0.7-3.5%).
	Discussion The authors summarised overall findings and referred to the previous evidences such as clinical practitioners, other weight loss programme in RCT and Look AHEAD (Action for Health in Diabetes) programme. They detailed all 3 programmes and compared each intervention to other similar programmes. The structured commercial weight loss programme with free prepared meals effectively promoted weight loss. Many components of this structured commercial programme included person-to-person behavioural counselling, low-energy density diet, prepackaged foods and increased exercise. Using free foods in prepackaged meals and snacks was a dietary pattern in order to reduce the risk for cardiovascular disease and stroke. Overweight and obese women achieved their weight loss during participating a free prepared meal and incentivised structured weight loss programme. There was greater weight loss in the structured weight loss programme over 2 years.
Generalisability	Not be able to generalise to other group of patients because of economic benefits and the dropout rate.
Other evidence	General comments Limitations: 1) This intervention programme was free of charge whilst patients who participated in this structured commercial programme needed to pay for enrolment fees and foods supplied. Thus, this is not able to generalise the findings. 2) Patients who participated in the intervention programme were more likely to highly motivate than others. 3) Unblinding the weight loss programme counsellors may affect patients' behaviour and effectiveness. And 4) The control group was also intervention so that the divergence between control and intervention groups could affect the findings. Recommendation for further study: The intervention programme with person-to-person behavioural counselling may corporate into medical practice that can include health care system and/or employer health promotion initiatives.
Funding	Jenny Craig Inc.

Rolland 2009[119]

Article identification: 3/2009	Reviewer's initials: SS	Verifier's initials: HB
Author and year: Rolland 2009		Country: UK
Objectives	Assessed the effectiveness of a low-carbohydrate/high-protein (LCHP), a commercial very low-calorie diet (VLCD) or LighterLife programme (LL), and a 600 kcal-deficient (CDD) diet in an obese population	
Methods		
Participants	Inclusion criteria: Men and women aged older than 18 with BMI ≥ 35 kg/m^2	
	Exclusion criteria: Patients with a history of hepatic or renal disease, cancer, pregnant or lactating, on antidepressant or anti-obesity medication, eating disorder	
	Settings and/or locations: Specialist Obesity Clinic	
	Duration: 9 months	
	Recruitment methods: Recruited patients by referring to a specialist obesity clinic	
	Sample size: 72 patients randomised	
Study design	Randomisation-sequence generation: Randomised controlled clinical trial 254 patients contacted, 120 obese patients assigned to a 600 kcal-deficient (CDD) diet for 3 months. 72 patients randomised. No further description	
	Allocation concealment: Insufficient information 34 patients allocated to LL group, and 38 patients allocated to LCHP group.	
	Implementation: Doctors implemented randomisation of patients to either LCHP or LL.	
	Blinding: Did not report	
	Statistical methods: 80% power used for power calculation with 2-sided type 1 error (α 0.5 level). Unpaired t tests were used to compare differences between groups whilst Repeat-measures ANOVA were used to compare differences within groups. ITT and completers analysis were performed after 3 and 9 months in both groups. Values presented as mean ± SD. Data analysis used SPSS V15.0.	
Intervention 1	9-month a commercial very low-calorie diet (Lighter Life, LL): Dietary intervention - Screening period: 3 months on the low-fat, reduced-energy diet (LFRE), 600 kcal. Dietary advice was reviewed at 2, 4, 8 and 12 weeks. Randomisation and diet allocation - Additional 3 months of maintaining weight loss > 5% of patients' body weight. Randomised to either LCHP or LL - Low-carbohydrate/high-protein diet (LCHP): Restricted to ≤ 40 g carbohydrate/day Energy intake ranged from 800-1500 kcal Given booklet with information about which foods to eat and which to avoid Supplemented with multivitamins and minerals	

Rolland 2009 (continued)

Methods	
Intervention 2 (continued)	- LL (VLCD): Administered soups, shakes and bars to replace conventional food Provided a daily average of 550 kcal Had 2 stages: 1) weight loss, 2) ongoing weight management. Attended weekly single-sex group meetings with 7-12 people at each stage. Delivered by a trained LL counsellor Enabled active management of motivation and concordance Used group support and counselling to encourage long-term behavioural modification and weight management. Group support consisted of a mix of research subjects and self-referred individuals. Remained on the weight loss phase for a minimum of 3 months as required and could be given a choice to continue for up to 6 months Reintroduced solid foods over a 12-week period Offered advice on healthy eating, exercise and continual support Came to the trial centres monthly for weighing the first 3 months and every other month after screening Also supported by telephone and email - Additional 6 months of maintaining weight loss > 10% of patients' body weight
Overall intervention	Started with a dietary treatment that included a low-fat, reduced-energy diet - If patients responded to this approach, they will be continued. - If patients failed to lose weight with a dietary treatment, they will be considered the alternative approach such as LCHP or prescription medication, reviewed monthly by dieticians and quarterly by doctors.
Outcomes	Primary outcome measures: Changes in weight Other outcome measures: body composition, waist and hip circumference, cardiovascular (CDV) risk but not extracted here
Results	
Participant flow	254 patients contacted, 120 patients assigned to a 600 kcal-deficient (CDD) diet for 3 months. 30 patients dropped out. 18 patients achieved 5% weight loss. 72 patients randomised. LL group: 34 patients allocated. 20 patients dropped out. 14 patients completed. LCHP group: 38 patients allocated. 18 patients dropped out. 20 patients completed.
Baseline data	Patients' characteristics in both LCPH and LL groups aged 42.7 (± 13.1) years and 39.9 (± 10.4) years with 35 women/3 men and 26 women/8 men, respectively.
Number analyzed	ITT: 34 and 38 patients in LL and LCHP groups, respectively Completers: 14 and 20 patients in LL and LCHP groups, respectively

Rolland 2009 (continued)

Results	Primary outcome: Weight loss

Table 1: Weight and BMI measured at baseline, month 3 and month 9, mean (± SD)

Measurement	Included LL, n = 34 and LCHP, n = 38			Completers only in LL, n = 14 and LCHP, n = 20		
	Screening	3 months*	9 months*	Screening	9 months	Change at 9 months
Weight, kg						
LCHP	111.6 (14.1)	108.7 (15.6)	109.6 (16.3)	110.4 (12.2)	109.1 (14.6)	-1.3 (4.5)
LL	122.6 (19.2)	111.0 (18.4)	107.5 (20.1)	129.6 (23.0)	98.0 (20.3)	-31.6 (22.0)
BMI, kg/m^2						
LCHP	41.6 (4.8)	40.6 (5.3)	40.9 (5.4)	40.8 (4.0)	40.3 (4.4)	-0.5 (1.7)
LL	46.0 (7.0)	41.8 (7.4)	40.3 (8.9)	47.0 (8.8)	35.0 (9.1)	-12.0 (9.7)

*Significant at p-value < 0.05

At 3 months, patients' mean weight change in the LL group (11.6 kg, 9.5%) were greater than those in LCHP group (2.8 kg, 2.5%) as well as BMI in the LL group (4.2 kg/m^2) and LCHP group (1.0 kg/m^2), respectively.

At 9 months with including LL and LCHP, patients' mean weight change in the LL group (15.1 kg, 12.3%) were greater than those in LCHP group (2.0 kg, 1.8%) as well as BMI in the LL group (5.7 kg/m^2) and LCHP group (0.7 kg/m^2), respectively.

At 9 months with completers, patients' mean weight change in the LL group (31.6 kg, 24.4%) were greater than those in LCHP group (1.3 kg, 1.2%) as well as BMI in the LL group (12 kg/m^2) and LCHP group (0.5 kg/m^2), respectively.

Weight loss between groups at 3 and 9 months was statistically significant difference (p < 0.05). This study showed that LL group was higher weight loss than LCHP group. Thus, the LighterLife programme recommended to improve weight loss.

Adverse events	Did not report
Discussions	
Interpretation	Introduction - Reviewed how importance of the effective weight loss and data from FORESIGHT report about obese UK adults, cost of obesity from NHS and policy - Reviewed the relevant studies about the effects of a variety of diets on weight loss in either short- or long-term and the meta-analysis of the efficacy and safety of a low carbohydrate diet - Described the matter of this study: Even though there were the previous studies of diets on weight loss, it remained uncertain to which diet is more effective to achieve long-term weight loss - Explained objectives of this study
	Methods Randomised controlled clinical trial: No definite procedure to generate randomisation sequence. However, 254 patients were contacted. 120 obese patients assigned to a 600 kcal-deficient (CDD) diet for 3 months. 72 patients were randomised. 34 patients were allocated to LL group, and 38 patients were allocated to LCHP group. Doctors implemented randomisation of patients to either LCHP or LL. Blinding was not applicable. Comparison of 2 diets: LL and LCHP groups Assessing outcomes: Measured weight by using bioelectrical impedance (Tanita BC-418 MA; Tanita, Arlington Heights IL, US). Weight values should be valid, however, there was no report of measuring height so that this value could be bias because of over or under estimation.

Rolland 2009 (continued)

Discussions	
Interpretation (continued)	Methods (continued) Provider: Dietician, doctor Statistical methods: Reported power calculation, *p*-value, tests used, ITT and completers analysis performed and programme analysed Power calculation could help this study for: 1) Scanning whether or not participants randomised were enough to see an effect and 2) preparing for sufficient participants if they declined to participate during the study.
	Results - Reported participants' flow, number of participant assignment, drop-out, randomisation and completers, and values in mean weight with SD - Both diet groups reported statistically significant differences at $p < 0.05$. - At 3 months, patients' mean weight change in the LL group (11.6 ± 12.9 kg) were significantly greater than those in LCHP group (2.8 ± 4.5 kg) as well as at 9 months, patients' mean weight change in the LL group (15.1 ± 21.1 kg) were greater than those in LCHP group (1.9 ± 5.0 kg) at $p < 0.001$.
	Discussion The authors summarised findings and discussed about the present obesity epidemic that developed several weight loss strategies. Comparing to other previous studies, findings were similar to Yancy study in terms of using high-protein diet on weight loss and Foster study to improve other risk factors related to obesity. However, this study found that the benefits of LHCP approaches were no longer than 9-month programme on weight loss. Also, there was no adverse event on hepatic or renal function that seems to be the same as other studies. Moreover, this study analysed weight changes e for the completers in both groups.
Generalisability	Did not report
Other evidence	General comments Recommendation for further study: Suggested to determine the long-term weight loss treatment. Limitations: Used simple randomisation to assign patients to their diets and no blinding Over 9 months of weight loss treatment, LL (VLCDs) was safe and effective to achieve weight loss.
Funding	LighterLife Ltd.

Shuger 2011[155]

Article identification: 4/2011	Reviewer's initials: SS	Verifier's initials: HB
Author and year: Shuger 2011		Country: US
Objectives	Determined the effectiveness of continuous self-monitoring and feedback of SenseWear™ Armband (SWA) alone and combination with group weight loss (GWL) to improve weight loss and waist circumference reduction over a 9-month period in sedentary overweight or obese adults	
Methods		
Participants	Inclusion criteria: Both men and women aged 18-64 years who were: - Underactive (Participants had no accumulating 150 minutes of moderate-to-vigorous physical activity throughout the week in bouts ≥ 10 minutes.) - Overweight or obese had BMI 25-45 kg/m^2 - Able to access to the Internet	
	Exclusion criteria: Participants who: - Lost weight > 20 lbs in the last 6 months - Elevated BP (160/95 mmHg) - Limited physical activity because of sickness - Had serious medical conditions or other issues e.g. pregnancy or depression that contraindicated or confounded the weight loss intervention	
	Settings and/or locations: The greater Columbia, South Carolina area	
	Duration: 9 months, February 2008-2009	
	Recruitment methods : Used a wide variety of techniques, newspaper, mailers, community events, worksite and other e-mail distributions	
	Sample size: Randomised controlled trial. 197 randomised	
Study design	Randomisation-sequence generation: Generated by computer.	
	Allocation concealment: Blocking for equal length with fixed numbers of treatment allotments in each group was used to balance treatment enrolments over time. Randomly assigned to one of the four groups 50 for standard care, 49 for GWL, 49 for GWL + SWA, 49 for SWA alone	

Table 1: Participants' drop-out and completing

Reasons of loss to follow-up	50 for standard care	49 for GWL	49 for GWL + SWA	49 for SWA alone
Time commitment	11	9	5	5
No contact	4	3	1	3
Family conflict	2	3	1	-
Medical condition	1	1	-	1
Relocated	1	1	-	1
Other	5	9	6	7

Shuger 2011 (continued)

Methods				
Study design: Allocation concealment (continued)				
Table 1: Participants' drop-out and completing (continued)				
Reasons of loss to follow-up	50 for standard care	49 for GWL	49 for GWL + SWA	49 for SWA alone
Number completed at				
Month 4	30	32	41	37
Month 9	26	28	37	32
Total	24	21	12	17

	Implementation: Did not report
	Blinding: Did not report
	Statistical methods: 80% power to detect an effect size of 0.81 (assuming $\alpha = 0.025$). SD was approximately assumed 7.0 for the baseline follow-up differences for 2 outcome measures of weight loss and waist circumference reduction. Descriptive baseline used mean ± SD or %. Data analysis used SAS V9.2
Intervention	There were two parts of the weight loss manual that were 1) a weight loss workbook with 14 chapters about healthy eating and active living and 2) a set of forms for participants to use to record their daily meal and lifestyle activity intake and physical activity.
Intervention 1	Group-based behavioural weight loss programme (GWL) Participants received: - 14 GWL sessions from a facilitator based on Active Living Every Day (ALED) and Healthy Eating Every Day (HEED) for the first four months - Highly emphasis on weight loss so that a weekly weigh-in was needed - Six one-on-one telephone counselling sessions to continue support and improve weight loss programme during the last five months.
Intervention 2	Armband alone group (SWA-alone) Participants received: - The SenseWear™ platform consisting of the armband, a real-time wrist watch display and access to a personalised Weight Management Solutions web account - A real-time feedback from the wrist watch on several outcomes (i.e. energy expenditure, minutes spent in moderate and vigorous exercise and steps for a day) whilst wearing the armband - Feedback regarding energy balance after they frequently uploaded their armband to the website and recorded daily energy intake and body weight to their web accounts - Reminder to wear the armband 16 hours a day, 7 days a week
Intervention 3	Combined GWL and SWA group (GWL + SWA) Participants received all components of the GWL and the SenseWear™ platform.
Comparison/ Control	Standard care Participants received a self-directed weight loss manual. The aim of this manual programme was to: - Help individuals adopt a healthful eating pattern and - Increase their physical activity levels through the use of cognitive and behavioural strategies

Shuger 2011 (continued)

Methods	
Outcomes	Primary outcome measures: Body weight (kg) Secondary outcome measures: BMI (kg/m^2) Other outcome measures: PA assessments, participant retention and adherence reported but not extracted here
Results	
Participant flow	787 participants were called for screening interviews. 277 Ineligible or not interested:
	- 2 not in the age criteria - 84 not in the BMI criteria - 30 being too active - 54 in medical exclusions - 10 no internet access - 48 in weight loss exclusions - 13 for activity limitations - 34 declined to participate or other
	510 individuals were eligible for orientation visit. 272 excluded: - 5 not in the BMI criteria - 36 in medical exclusions - 20 being CESD (Cholesteryl Ester Storage Disease) - 211 declined to participates or other
	238 individuals were eligible for run-in visits. 14 excluded: - 3 high blood pressure - 4 for activity logs - 7 declined to participates or other
	224 individuals were eligible for baseline visit. 27 excluded: - 3 not in the BMI criteria - 24 not in the BMI criteria
Baseline data	

Table 2: Participants' characteristics at baseline

Characteristics	Total, n = 197*	Standard care, n = 50*	GWL, n = 49*	SWA alone, n = 49*	GWL + SWA, n = 49*
Age, years	46.9 (10.8)	47.2 (8.9)	46.8 (12.4)	47.7 (11.6)	45.7 (10.4)
Female, %	161 (81.7)	42 (84.0)	39 (79.6)	40 (81.6)	40 (81.6)
Weight, kg	92.8 (18.4)	94.2 (18.2)	93.2 (18.6)	92.0 (21.0)	91.9 (15.7)
BMI, kg/m^2	33.3 (5.2)	33.7 (5.5)	33.1 (4.8)	33.2 (5.4)	33.0 (5.0)

*mean (± SD) or N (%)

Shuger 2011 (continued)

Results	
Participants' characteristics in all diet groups were mainly female and aged about 47 years with mean weight 93 kg and mean BMI 33 kg/m^2, approximately.	
Number analyzed	ITT from each group included in primary analysis
Outcomes and estimation	

Table 3: Weight and BMI mean differences over time

		Standard care, n = 50*	GWL, n = 49*	SWA alone, n = 49*	GWL + SWA, n = 49*
Weight, kg**	BL	102.22 (2.97)	101.84 (2.95)	101.15 (2.95)	100.32 (2.97)
	M4	101.23 (3.03)	100.74 (2.99)	98.48 (2.97)	96.83 (2.99)
	M9	101.32 (3.05)	99.98 (3.00)	97.60 (2.99)	93.73 (2.99)
p-value	BL vs. M4	0.32	0.23	0.003	< 0.0001
	BL vs. M9	0.39	0.05	0.0002	< 0.0001
BMI, kg/m^{2**}	BL	34.52 (0.91)	34.54 (0.90)	34.73 (0.90)	34.39 (0.91)
	M4	34.12 (0.93)	34.21 (0.92)	33.83 (0.91)	33.13 (0.91)
	M9	34.16 (0.94)	33.84 (0.92)	33.56 (0.92)	32.11 (0.92)
p-value	BL vs. M4	0.25	0.31	0.003	< 0.0001
	BL vs. M9	0.32	0.03	0.0005	< 0.0001

Notes: BL = Baseline, M4 = Month 4, M9 = Month 9, SE = Standard error

*mean (± SE), **Significantly different from Standard care

At 9 months, participants' mean weight loss in all 3 intervention groups was statistically significant difference from Standard care (0.9 kg, 0.9%), GWL (1.86 kg, 1.83%), SWA alone (3.55 kg, 3.5%) and GWL plus SWA (6.60 kg, 6.6%). As a result, participants who participated in GWL plus SWA decreased greater weight loss than other groups. Therefore SWA could support group-based behavioural weight loss education to improve people weight.

Adverse events	Did not report
Discussions	
Interpretation	Introduction - Reviewed the prevalence of obese US adults increased 30% of US population, obesity defined as risk factor for health chronic conditions, people attempts to lose weight by participating in the clinical and commercial weight loss interventions for a short-term treatment and one weight loss approach as self-monitoring - Defined a new weight loss intervention and described in details how this works - Described the matter of this study: Self-monitoring has not been done in a new weight loss intervention - Hypothesis: Group weight loss intervention with continuous self-monitoring, a SenseWearArmband (SWA), interactive weight loss software and a weight loss manual would produce greater weight loss than a similar intervention without SWA and self-monitoring. - Explained the aim of this study

Shuger 2011 (continued)

Discussions	
Interpretation (continued)	Methods Randomised controlled trial: Randomisation sequence was generated by computer and blocking for equal length with fixed numbers of treatment allotments in each group was used to balance treatment enrolments over time. 197 participants were randomised and assigned to one of the four groups. 50 participants were allocated to standard care and 49 participants each were allocated to GWL, GWL + SWA and SWA alone, respectively. Implementation and blinding were not applicable. Comparison of 4 groups: Standard care (control group), group-based behavioural weight loss education (GWL), Combined GWL and SWA group (GWL + SWA) and Armband alone group (SWA alone). Assessing outcomes: Measured weight by using a calibrated balance-beam scale. Weight value should be valid, however there was no report of measuring height so that this value could be bias because of over or under estimation. Providers: NA, however, there were a facilitator from ALED and HEED. Statistical methods: Reported power calculation, *p*-value, however, values presented, tests used and programme analysed, however, confidence intervals were unavailable. Power calculation could help this study for: 1) Scanning whether or not participants randomised were enough to see an effect, 2) not wasting time on an underpowered study and 3) preparing for sufficient participants if they declined to participate during the study.
	Results - Presented participants' flow and number of ineligible or not interested participants, randomisation, exclusion, run-in visit, allocation and ITT and completers analysis, and also reported values reported in mean weight with SE - All 4 groups reported statistically significant differences at $p \leq 0.01$. - At 9 months, participants' mean weight loss in all 3 intervention groups was statistically significant different from Standard care (0.89 kg, $p = 0.39$), GWL (1.86 kg, $p = 0.05$), SWA alone (3.55 kg, $p = 0.0002$) and GWL plus SWA (6.60 kg, $p = 0.0001$). As a result, participants who participated in all 3 interventions decreased greater weight loss than standard care.
	Discussion The authors referred to the primary aim of this study, summarised findings and described details of SWA approach as a new weight loss strategy and how SWA affected in the different time point. Based on other evidences, they discussed about studies and systematic review of weight loss self-monitoring. The aspect of this present study was compared to other studies in terms of self-monitoring of diet and physical activity with the SWA and other self-monitoring approaches. The use of self-monitoring was suggested and could predict the successful weight loss in technology-assisted weight reduction programmes. Strength for the primary outcome was a randomised design. Limitations: 1) A large attrition rate, 2) Mostly female, 3) A short intervention and 4) No well performance in GWL.
Generalisability	Not generalisabiltiy but acceptable
Other evidence	General comments This is a new weight loss intervention by using technology to reach individuals' weight with self-monitoring. Further study: A new weight loss intervention can improve health lifestyle change and precisely assess free-living energy balance and increase the understanding of the contribution of energy intake/expenditure to weight loss
Funding	BodyMedia, Inc

Truby 2006[126]

Article identification: 1/2006	Reviewer's initials: SS	Verifier's initials: HB
Author and year: Truby 2006		Country: UK
Objectives	Compared the effectiveness of 4 commercial weight loss diets available to UK adults	
Methods		
Participants	Inclusion criteria: Participants aged 18-65 years with BMI 27-40 kg/m^2.	
	Exclusion criteria: Participants had coronary heart disease, type 1 or 2 diabetes, renal, liver, respiratory failure, gout, obesity with Cushing's disease or hypothyroidism, previous gastric or weight loss surgery, clinical depression, eating disorders, drug or alcohol misuse, malabsorptive state, took lipid lowering or anti-hypertensive drugs, taking any drugs for weight loss (orlistat and sibutramine), treated for cancer, pregnant or breastfeeding.	
	Settings and/or locations: Community based sample of healthy overweight and obese adults, 5-region centres at Surrey University, Bristol University, Nottingham University, Ulster (Caleraine) University and Queen Margaret University College, Edinburgh)	
	Duration: 6 months started date in July 2002	
	Recruitment methods: Recruited participants by a BBC advertising campaign (television and other forms of media). Participants were selected from people who lived within 30 miles of a test centre.	
	Sample size: 293 participants randomised (214 women, 79 men)	
Study design	Randomisation-sequence generation: Multicentre randomised unblinded controlled parallel dietary intervention. Stratification was used to generate randomisation sequence in each test centre by following participants' sex.	
	Allocation concealment: A group using random number generation allocated them to individual group. 300 people enrolled to baseline screening. 60 participants each estimated to allocate in 5 groups. At least 44 participants completed in each group, approximately. 57 participants in Atkins, 58 participants in Weight Watchers (WW), 59 participants in Slim-fast, 58 participants in Rosemary Conley, 61 participants in Control	
	Implementation: Investigators implemented randomisation.	
	Blinding: Un-blinded investigators and participants	
	Statistical methods: 80% power was used for sample size calculation with significant at $p < 0.05$. ITT analysis with baseline values carried forward (BCF) used to analyse the primary outcome. Using ANOVA was to compare differences between groups as well as post hoc pairwise testing with Tukey's HSD (honestly significantly different) tested a significant effect. Also, using t tests for continuous variables and χ^2 for categorical variables were to compare differences between participants over time.	
Intervention 1	Dr Atkins' new diet revolution (a self monitored low carbohydrate eating plan): Participants were given a copy of Dr Atkins New Diet Revolution.	
Intervention 2	Weight Watchers (WW) pure points programme (an energy controlled diet with weekly group meetings, group-based programme): Participants attended the most convenient class that can be reimbursed the cost participated one class per week.	
Intervention 3	Slim-fast plan (a meal replacement approach): Participants could reimburse the 2 meal replacements for a day and were provided a copy of the Slim-fast support pack.	

Truby 2006 (continued)

Methods	
Intervention 4	Rosemary Conley's eat yourself slim diet and fitness (a low fat diet and a weekly group exercise class, group-based programme)
Comparison/ Control	A delayed treatment control group: Maintained weight by diet and exercise pattern. This control group offered participants diets for 6 months at the end of study and also was a free of charge programme.
All groups	Participants recorded a 7-day diet and physical activity at baseline, 8 weeks and 24 weeks. At week 10, participants were offered a free daily multivitamin. At 12 months, dieting behaviour and weight change were recorded.
Outcomes	Primary outcome measures: Weight changes over 6 months, measured at baseline, 2 and 6 months Another main outcome measures: Body fat changes but not extracted here
Results	
Participant flow	300 participants recruited. 7 participants excluded. 293 participants randomised. 57 participants in Atkins, 58 participants in WW, 59 participants in Slim-fast, 58 participants in Rosemary Conley, 61 participants in Control Excluded: 17 participants in Atkins, 11 participants in WW, 17 participants in Slim-fast, 17 participants in Rosemary Conley, 21 participants in Control Completers at 24 weeks: 40 participants in Atkins, 47 participants in WW, 42 participants in Slim-fast, 41 participants in Rosemary Conley, 40 participants in Control
Baseline data	

Table 1: Baseline characteristics of participants in the BBC diet trials, mean (± SD)

Characteristic	Atkins, n = 57	Weight Watchers, n = 58	Slim-fast, n = 59	Rosemary Conley, n = 58	Controls, n = 61
Men/Women	15/42	16/42	17/42	16/42	15/46
Age, years	40.9 (9.7)	39.9 (10.9)	38.9 (10.7)	40.6 (10.3)	40.8 (9.6)
Weight, kg	90.3 (12.7)	88.8 (13.3)	90.1 (14.1)	89.8 (12.9)	87.9 (13.5)
BMI, kg/m^2	31.9 (2.2)	31.2 (2.7)	32.2 (3.0)	31.6 (2.6)	31.5 (2.9)

Participants' characteristics in all groups were mostly women, aged approximately 40.2 years with mean weight 89.4 kg and mean BMI 31.7 kg/m^2.

Number analyzed	ITT: 57 participants in Atkins, 58 participants in WW, 59 participants in Slim-fast, 58 participants in Rosemary Conley, 61 participants in Control Completers: 40 participants in Atkins, 47 participants in WW, 42 participants in Slim-fast, 41 participants in Rosemary Conley, 40 participants in Control

Truby 2006 (continued)

Results	
Outcomes and estimation	

Table 2: Intention to treat analysis of main outcomes in participants in the BBC diet trials, mean (± SD)

Outcome	Atkins, n = 57	Weight Watchers, n = 58	Slim-fast, n = 59	Rosemary Conley, n = 58	Controls, n = 61
Weight loss, kg					
0-2 months	5.2 (4.4)	4.7 (3.2)	3.7 (3.5)	4.0 (3.3)	0.4 (1.8)
2-6 months	1.3 (3.1)	2.2 (3.0)	1.4 (2.8)	2.4 (3.4)	-0.9 (1.6)
0-6 months	6.0 (6.4)	6.6 (5.4)	4.8 (5.6)	6.3 (6.1)	-0.6 (2.2)
Weight loss, %					
0-2 months	5.5 (4.2)	5.1 (3.5)	3.8 (3.4)	4.5 (3.6)	0.4 (2.2)
2-6 months	1.3 (3.1)	2.4 (3.4)	1.3 (2.9)	2.7 (3.7)	-1.2 (1.9)
0-6 months	6.2 (6.2)	7.3 (6.1)	4.9 (5.5)	7.0 (6.6)	-0.6 (2.7)

Notes: The control group was significantly different from all other groups at $p < 0.001$.

During the first 2 months, participants' mean weight change in Atkins diet (5.2 kg, 5.5%) was greater than WW (4.7 kg, 5.1%), Rosemary Conley (4.0 kg, 4.5%) and Slim-fast (3.7 kg, 3.8%), respectively. However, at 6 months, participants' mean weight change in WW diet (6.6 kg, 7.3%) was greater than Rosemary Conley (6.3 kg, 7.0%), Atkins (6.0 kg, 6.2%) and Slim-fast (4.8 kg, 4.9%), respectively.

There were not statistically significant differences of mean weight loss over time. Although WW was greater weight loss than other diets at month 6, there was no more or less effective than other diets. This study provided the effects of commercial weight loss programmes and help people to select which programmes were appropriate to their weight loss goal and to the period of being weight loss treatment.

Adverse events	Did not report
Discussions	
Interpretation	Introduction - Reviewed the prevalence of obesity in the UK, proportion of overweight adults, cost of obesity from NHS, commercial weight loss programme (Weight Watchers) and self-help programme (Atkins) - Reviewed the relevant studies in the US - Described the matter of this study: Limited on evidences of commercial diets - Explained the popular commercial weight loss programmes and objectives of this study
	Methods Multicentre randomised unblinded controlled parallel dietary intervention Randomisation sequence was generated by stratification in each test centre and following participants' sex. A group using random number generation allocated them to individual group. 300 people enrolled randomly to baseline screening. 60 participants each were allocated to 5 groups. Investigators implemented randomisation. Investigators and participants were un-blinded. Comparison of 5 diet groups: Atkins, WW, Slim-fast, Rosemary Conley and Control groups. At baseline, no statistically significant differences.

Truby 2006 (continued)

Discussions	
Interpretation (continued)	Methods Assessing outcomes: Measured weight in light clothing monthly (would be valid), but no report of height value (may be bias because of over or under estimation) Provider: Health care professional Statistical methods: Although there was no report of programme analysis used, the tests presented in this study were from SPSS. Reported power calculation, significant level at $p < 0.05$, tests used, and ITT analysis with baseline values carried forward (BCF) Power calculation could help this study for: 1) Scanning whether or not participants randomised were enough to see an effect and 2) preparing for sufficient participants if they declined to participate during the study.
	Results - Reported participants' flow and number of exclusion, randomisation, allocation, withdrawal and completers, and also presented values in mean weight with SD - All 5 groups reported statistically significant differences at $p < 0.05$. At baseline, there was no significant difference among diet groups. At any particular time point, mean weight loss was not significant difference among all diet groups. However, at the end of the programme, participants' mean weight change in all diet groups was 5.9 kg.
	Discussion The authors summarised this study in terms of clinical benefits such as decreasing in waist circumference and BP. The higher weight lost, the more BP and WC reduced. All 4 weight loss approaches were similarly effective after 6 months. Based on other evidences, this study compared to those and also found that effective weight loss was similar. However, more information was needed for health care professionals in order to decide which dietary supplements suited patients. Thus, this study could not predict the best approach for each person to either lose or maintain weight in the longer term.
Generalisability	Did not report
Other evidence	General comments No report of limitations, however, recommendation for further study could be suggested a larger number of group members and weight maintenance. Commercial weight loss programme could assist the uncomplicated obese adults. Findings provided the weight loss goal by dieting and practitioner managing and information on the best effect to highly motivate participants for improving weight loss over one year.
Funding	The BBC

Van Wier 2011[157]

Article identification: 5/2011	Reviewer's initials: SS	Verifier's initials: HB
Author and year: Van Wier 2011		Country: Netherlands

Objectives	Determined the effectiveness of a weight-management programme with personal counselling by phone or e-mail
Methods	
Participants	Inclusion criteria: Employees aged ≥ 18 years, had BMI ≥ 25 kg/m^2, paid employment ≥ 8 hours a week, could read and write Dutch and access to the Internet either at work or at home.
	Exclusion criteria: Had pregnant, diagnosis or treatment for disorders that made exercise difficult and BMI < 25 kg/m^2
	Settings and/or locations: 7 Dutch service-sector companies
	Duration: 6 months between January and August 2004 and follow-up at 2 years
	Recruitment methods: 21,000 employees screened by questionnaire
	Sample size: 1386 employees randomised
Study design	Randomisation-sequence generation: Randomly assigned the eligible employees to one of the three study groups by using blocks of 18. No further description At the 2-year follow-up, if participants did not respond the postal questionnaire, they will receive a maximum of 5 reminders (post, e-mail and phone). The drop-out participants received a once-only letter in order to ask them whether or not they would take part in the final weight measurement. They withdrew because of pregnancy or dissatisfaction.
	Allocation concealment: The sequence generated by number and opaque envelopes. Three study groups were phone group (n = 462), Internet group (n = 464) and control group (n = 460).
	Implementation: By statisticians
	Blinding: Did not report
	Statistical methods: Used 2-sided t tests and chi-square tests to compare baseline values in groups with complete and incomplete data Sample size calculation: Selected 90% power in 2-tailed tests at a significance level of 0.05 Missing follow-up weight was multiply imputed for the primary analysis of body weight. To examine effectiveness, analyses were based on group allocation, regardless of the actual intervention received or of adherence to the intervention.
Intervention	Both intervention groups, participants: - Received self-help brochures about overweight, healthy diet and exercise - Accessed to a lifestyle intervention programme, the principles of behaviour modification consisted of 10 modules that provided information on nutrition and exercise, behaviour modification strategies (e.g. self-monitoring, goal-setting) - At the end of each module, participants were contacted by their personal counsellor. There were counselling team included 2 dieticians and 2 physical activity scientists for a maximum of 6 months. The phone group, participants received the programme in the workbook form.

Van Wier 2011 (continued)

Intervention (continued)	The Internet group, participants: - Accessed the programme through an interactive Website - Had no prescription of diet or physical activity - Supported to set their own behavioural goals
Control	Participants only received self-help brochures about overweight, healthy diet and physical activity.
Outcomes	Primary outcome measures: Body weight change Regarding to body weight, 3 outcomes were: 1) weight change at follow-up, 2) likeliness of achieving a decrease of at least 5% of initial weight and 3) weight change from 6 months to 2 years.
Results	
Participant flow	4619 participants were eligible on screening questionnaire. 2004 participants excluded. 2615 were invited to participate. 1161 had no or late response. 1454 participants had appointment at baseline measurement. 57 participants did not show-up. 1397 were eligible to assess at baseline measurement. 11 excluded with reasons: 9 BMI < 25kg/m^2, 1 pregnant and 1 withdrawal. 1386 participants randomised. 462 participants in phone group, 464 participants in Internet group and 460 participants in control group. Phone group: 199 participants excluded. 263 participants completed. Internet group: 201 participants excluded. 263 participants completed. Control group: 194 participants excluded. 266 participants completed.

Baseline data

Table 1: Baseline characteristics by intervention group

	Phone, n = 462	Internet, n = 464	Control, n = 460	All, n = 1386
Male, n (%)	321 (69.5)	302 (65.1)	306 (66.5)	929 (67.0)
Age, mean (± SD), years	43 (8.8)	43 (8.4)	43 (8.7)	43 (8.6)
BMI, mean (± SD), kg/m^2	29.5 (3.5)	29.6 (3.4)	29.6 (3.7)	29.6 (60.4)

Participants' characteristics in all diet groups were higher men (67%), aged 43years and had mean BMI 29.6 kg/m^2 and mean weight 93.2 kg, approximately.

Number analyzed	ITT: Did not report, completers 263 in phone group, 263 in Internet group and 266 in control group

Van Wier 2011 (continued)

Results

Outcomes and estimation

Table 2: Body weight at baseline and 2-year follow-up

	Phone		Internet		Control	
	Baseline	Follow-up	Baseline	Follow-up	Baseline	Follow-up
Multiply imputed datasets						
Body weight	n = 453		n = 450		n = 448	
Mean (± SD), kg	93.6 (14.0)	92.1 (13.7)	92.9 (14.4)	91.0 (14.4)	93.0 (13.4)	92.0 (13.2)
≥ 5% weight loss, n (%)	-	100 (22.1)	-	101 (22.4)	-	71 (15.9)
Complete cases						
Body weight	n = 263		n = 241		n = 241	
Mean (± SD), kg	92.3 (13.0)	90.9 (13.3)	91.5 (13.7)	89.6 (13.9)	91.3 (12.4)	90.6 (12.9)
≥ 5% weight loss, n (%)	-	53 (20.2)	-	51 (19.4)	-	35 (13.2)

At 2-year follow-up, participants' mean weight loss in phone group (1.5 kg, 1.6%) and Internet group (1.9 kg, 2.0%) was greater than those in Control group (1.0 kg, 1.1%) as well as in complete cases, participants' mean weight loss in phone group (1.4 kg, 1.5%) and Internet group (1.9 kg, 2.0%) was greater than those in Control group (0.7 kg, 0.8%).

Table 3: Differences between intervention groups in body weight

Variable	Multiply imputed datasets		Complete cases	
	Difference (95% CI)	*p*-value	Difference (95% CI)	*p*-value
Body weight 0-24 mo, kg				
Phone vs control	-0.4 (-1.4 to 0.7)	0.448	-0.8 (-1.5 to 0.03)	0.059
Internet vs control	-0.9 (-2.0 to 0.3)	0.112	-1.2** (-1.9 to -0.4)	0.004
Internet vs phone	-0.5 (-1.2 to 0.2)	0.142	-0.4 (-1.2 to 0.4)	0.314
Body weight 6-24 mo,* kg				
Phone vs control	0.5 (-1.3 to 2.3)	0.470	0.4 (-0.4 to 1.1)	0.360
Internet vs control	-0.7 (-1.7 to 0.3)	0.162	-0.6 (-1.4 to 0.1)	0.096
Internet vs phone	-1.0** (-1.7 to -0.3)	0.009	-1.0** (1.7 to 0.4)	0.009

*Adjusted for baseline body weight, **Significant difference at $p < 0.05$

Van Wier 2011 (continued)

Results	
Outcomes and estimation (continued)	
Comparing weight loss programmes among groups, there were statistically significant differences between Internet and control groups (p = 0.004) and Internet and phone groups (p = 0.009).	
Adverse events	Did not report
Discussions	
Interpretation	Introduction - Reviewed the prevalence of overweight adults in Netherlands, proportion of overweight adults increased between 1990 and 2009, health risk factors related obesity - Reviewed the relevant studies about systematic review in the US emphasized on the effectiveness of weight loss, types of programme and advantages of the programme - Described the matter of this study: No studies providing phone counselling in a-long term treatment and no additional knowledge on how the effectiveness of telecommunication weight loss interventions was superior than others - Explained 2 aims of this study
	Methods Randomisation sequence was generated by using blocks of 18 from the eligible employees to one of the three study groups following number and opaque envelopes. 1386 employees were randomised. 462 employees were allocated to phone group, 464 allocated to Internet group 460 to control group. Randomisation was implemented by statisticians. Blinding was not applicable. Comparison of 3 groups: Phone, internet and control groups Assessing outcomes: Measured weight with a digital scale (Seca 770, Seca GmbH & Co, Hamburg, Germany). Weight value should be valid, however there was no report of measuring height so that this value could be bias because of over or under estimation. Provider: Counsellor Statistical methods: Reported power calculation, p-value, tests used and programme analysed There was 90% power calculation to detect a mean weight loss of sample size between 2 groups in or to scanning whether or not participants randomised were enough to see an effect and to prepare for sufficient participants if they declined to participate during the study.
	Results - Reported participants' flow and number of exclusion, randomisation, allocation, dropout and completers, and presented values in mean weight with SD and 95% CI in multiply imputed datasets and complete cases - All groups reported statistically significant differences at $p < 0.05$. - Comparing weight loss programmes among complete cases, weight loss in the Internet group was 1.2 kg (95% CI: -1.5 to 0.4) and in the phone group 0.8 kg (95% CI: -1.5 to 0.03) compared with control groups.
	Discussion The authors summarised main findings of this study and referred to reasons of determining effectiveness of phone and e-mail on weight control counselling. Consequently, counselling was described. The authors also explained reasons of selecting employees and the matter of this study, and discussed results found by complete-case analysis. However, there were few studies of weight reduction have done in the work setting for 6 months but no studies in this setting for 18 months. As a consequence, results of this study could not compare to other previous studies. They confirmed that there was no significant difference in weight loss between usual care and phone counselling.

Van Wier 2011 (continued)

Discussions	
Interpretation (continued)	Discussion (continued) Discussion is acceptable because the authors summarised and discussed by following the primary and secondary aims. They proposed the further aim will be evaluating the effects of the intervention on WC, diet and physical activity.
Generalisability	Did not report
Other evidence	General comments Limitations: The rate of loss to follow-up and missing weight data Strengths: A theory-based intervention was adapted to the Dutch occupational setting, the broad selection criteria, the objective of measuring weight for the majority of participants, the substantial sample size and the long-term study. Future work: Methods to improve retention
Funding	The Netherlands organisation for Health Research and Development supported the study funds within the Prevention Programme, the Netherlands Heart Foundation and Body@Work.

Womble 2004[113]

Article identification: 1/2004	Reviewer's initials: SS	Verifier's initials: HB
Author and year: Womble 2004		Country: US
Objectives	Assessed the efficacy of eDiet.com (a commercial Internet weight loss programme) to improving weight, cardiovascular health and quality of life	
Methods		
Participants	Inclusion criteria: Women aged 18-65 years with BMI 27-40 kg/m^2.	
	Exclusion criteria: If participants - Had type 1 or 2 DM, BP > 140/90 mm Hg, history of cerebrovascular, cardiovascular, kidney or liver disease - Used medications e.g. steroids - Had pregnancy or lactation, weight loss ≥ 5% of initial weight and/or use of anorectic agents in the last 6 months, psychosocial contraindications e.g. bulimia nervosa, major depression or other psychiatric illness	
	Settings and/or locations: University of Pennsylvania	
	Duration: 1 year	
	Recruitment methods: Recruited participants via telephone calls. Participants were interviewed by a clinical psychologist 158 Eligible via phone: 65 Ineligible, 93 Eligible via clinic visit (46 Ineligible)	
	Sample size: 47 participants randomised	
Study design	Randomisation-sequence generation: Randomised controlled trial conducted from February 2001 to September 2002. No further description	
	Allocation concealment: No description. 47 participants randomised. 23 participants were assigned to eDiets.com, and 24 participants were assigned to LEARN (Weight loss manual).	
	Implementation: Did not report	
	Blinding: Did not report	
	Statistical methods: The percentage of power calculation was 80% with α 0.05 level. Using Student's t tests for independent samples was to compare differences between groups at baseline whilst repeated-measures ANOVA was to evaluate weight change over time. A last-observation-carried-forward (LOCF) analysis, a baseline-carried-forward (BCF) analysis and a completers analysis were used to present in this study. Data analysis used SPSS V11.5.	
Intervention	Internet weight loss programme: Virtual visit with dietician BMI 27-35 kg/m^2 with meal plan ~1200-1300 kcal/d, BMI > 35 kg/m^2 with meal plan 1300 - 1400 kcal/d Assisted purchasing appropriate foods Provided social support: On-line meeting by professional, on-line bulletin board, fitness instructors, 24 h/d help desk, e-mail reminders about the programme and their goals, bi-weekly diet and fitness e-mail newsletter, allowed members to find a buddy Met a psychologist at baseline, weeks 8, 16, 26 and 52: 20 minutes/set Recorded food intake daily during the first 16 weeks	

Womble 2004 (continued)

Methods	
Comparison/ Control	Weight loss manual: Given a copy of LEARN Program for Weight Management 2008 A 243-page book: Provided 16 step-by-step lessons for modifying eating, activity and thinking habit Instructed women to consume a 1200-to-1500-kcal/d self-selected diet of conventional table foods, kept daily records of food intakes and the number of calorie consumed Encouraged physical activity by walking up to 30 min/day Practiced other weight control behaviours
Outcomes	Primary outcome measures: Weight change Secondary outcome measures: Cardiovascular health and quality of life not extracted here
Results	
Participant flow	158 participants were eligible. 65 participants excluded. 93 participants were eligible via clinic visit. 46 participants excluded. 47 participants randomised. 23 participants were assigned to eDiets.com, and 24 participants were assigned to LEARN (Weight loss manual). At week 16, 15 participants completed in eDiets.com, and 16 participants completed in Weight loss manual. At week 52, 8 participants each lost to follow-up in eDiets.com and in Weight loss manual.
Baseline data	Table 1: Participants' baseline characteristics*

Variables	eDiets.com, n = 23	Weight loss manual, n = 24
Age, years	44.2 (9.3)	43.3 (11.1)
Weight, kg	93.4 (12.6)	87.9 (10.8)
BMI, kg/m^2	33.9 (3.2)	33.0 (3.0)

*Values shown are mean (± SD), There were no statistically significant differences between the two groups.

	All participants were women. Participants' characteristics in both eDiet.com and weight loss manual aged approximately 43.8 years with mean weight 90.7 kg and mean BMI 33.5 kg/m^2.
Number analyzed	ITT: 23 participants were assigned to eDiets.com, and 24 participants were assigned to LEARN (Weight loss manual). Completers: 15 participants in eDiets.com, 16 participants in weight loss manual

Womble 2004 (continued)

Results	
Outcomes and estimation	

Table 2: Percentage of weight reduction for participants at week 16 and 52, mean (± SD)

Condition	LOCF (%)	BCF (%)	Completers only (%)
eDiets.com, n	23	23	15
Week 16	0.9 (3.2)	0.9 (3.1)	1.3 (3.3)
Week 52	1.1 (4.0)	1.3 (3.3)	2.1 (3.9)
Weight loss manual, n	23	23	16
Week 16	3.6 (4.0)	3.2 (5.5)	4.0 (3.7)
Week 52	4.0 (5.1)	3.1 (4.6)	4.4 (5.0)

At 16 weeks with LOCF analysis, participants' mean weight change in eDiets.com (0.9%) was lower than those in the weight loss manual (3.6%) as well as at 52 weeks, weight in eDiets.com (1.1%) was lower than those in the weight loss manual (4.0%), respectively.

At 16 weeks with BCF analysis, participants' mean weight change in eDiets.com (0.9%) was lower than those in the weight loss manual (3.2 %) as well as at 52 weeks, weight in eDiets.com (1.3%) was lower than those in the weight loss manual (3.1%), respectively.

At 16 weeks with completers analysis, participants' mean weight change in eDiets.com (1.3%) was lower than those in the weight loss manual (4.0%) as well as at 52 weeks, weight in eDiets.com (2.1%) was lower than those in the weight loss manual (4.4%), respectively.

Weight loss between groups at 16 and 52 weeks was statistically significant difference ($p < 0.05$). This study showed that eDiets.com was lower weight loss than the weight loss manual group. Although a commercial Internet weight loss improved weight, this programme lost weight less than a traditional behavioural weight control programme at the same period.

Adverse events	Did not report
Discussions	
Interpretation	Introduction - Reviewed the ratio of US overweight and obese adults and discovering the successful weight loss interventions in the public health and found that group behavioural weight loss programme was broadly, however, those people concern about type of the programme, time of being in the weight loss programme and how convenience the clinic visit will be. - Reviewed the recent study about the weight loss programme conditions such as group meeting, length of treatment and setting - Described the matter of this study: No studies of the commercial Internet weight loss programme presented results from RCT - Hypothesis was individuals who participated in Internet programme lost more weight than manual programme - Explained objectives of this study
	Methods Randomised controlled trial: No report of how to generate randomisation sequence, however, 47 participants were randomised. 23 participants were allocated to eDiets.com, and 24 participants were allocated to LEARN (Weight loss manual). Implementation and blinding were not applicable. Comparison of 2 groups: eDiets.com and LEARN (Weight loss manual). At baseline, no statistically significant differences.

Womble 2004 (continued)

Discussions	
Interpretation (continued)	Methods (continued) Assessing outcomes: Measured weight without shoes to the nearest 0.1 kg. Weight value should be valid, however there was no report of measuring height so that this value could be bias because of over or under estimation. Provider: A clinical psychologist, family physician Statistical methods: Reported power calculation, *p*-value, tests used, programme analysed, and 3 analyses of LOCF; BCF and completers, however, confidence intervals were unavailable. Power calculation could help this study for: 1) Detecting a difference among groups to scan whether or not participants randomised were enough to see an effect and 2) preparing for sufficient participants if they declined to participate during the study.
	Results - Reported participants' flow, number of eligible participant, exclusion, randomisation, completion and loss to follow-up - Reported values in mean weight with SD - Both groups reported statistically significant differences at $p < 0.05$. - At 16 weeks with LOCF analysis, participants' mean weight change in eDiets.com (0.9 ± 3.2%) was lower than those in the weight loss manual (3.6 ± 4.0%) as well as at 52 weeks, weight in eDiets.com (1.1 ± 4.0%) was lower than those in the weight loss manual (4.0 ± 5.1%), respectively. Participants in the manual group significantly lost more weight than those in eDiets.com.
	Discussion The authors summarised main findings in terms of the successful weight loss and 2 factors related were convenience (time and travel) and structure (type of programme). Based on other previous evidences, this study was compared to the manual weight loss programme (LEARN) and found that results were similar success in weight reduction. As 2 factors mentioned, it seemed to limit the potential benefits of eDiets.com were 1. The minimal use of the services: Depended on participants' convenient and 2. Structure concern: Did not follow step-by-step as LEARN approach. The authors also concluded that this study was the first evaluation of a commercially-based Internet weight loss programme. However, consumers were less likely to clinically achieve weight loss which provided mainly details in diets and exercise.
Generalisability	Did not report
Other evidence	General comments Recommendation for further study: Larger sample size in both men and women, needed to assess other internet-based weight loss programmes, always obtained counting number of times of participants log on to the web site including length of visits Using a commercially-based Internet weight loss programme was not as successful as a weight loss manual. The reason was that the Internet programme mostly provided the information about diet and exercise as well as the traditional weight loss programme.
Funding	The North American Association for the Study for the Study of Obesity and NIH

Appendix 6 Ethical approval to the pilot study

The University of Nottingham

Division of Social Research in Medicines and Health

Research Ethics Approval Form

Name Sukhamaphorn Sriwisit

Superviser(s) Helen Boardman, Tony Avery

Course of Study MPharm

Title of research project: :. Evaluation of a pharmacist led weight management clinic.

Is this a resubmission? No

Comments

Outcome

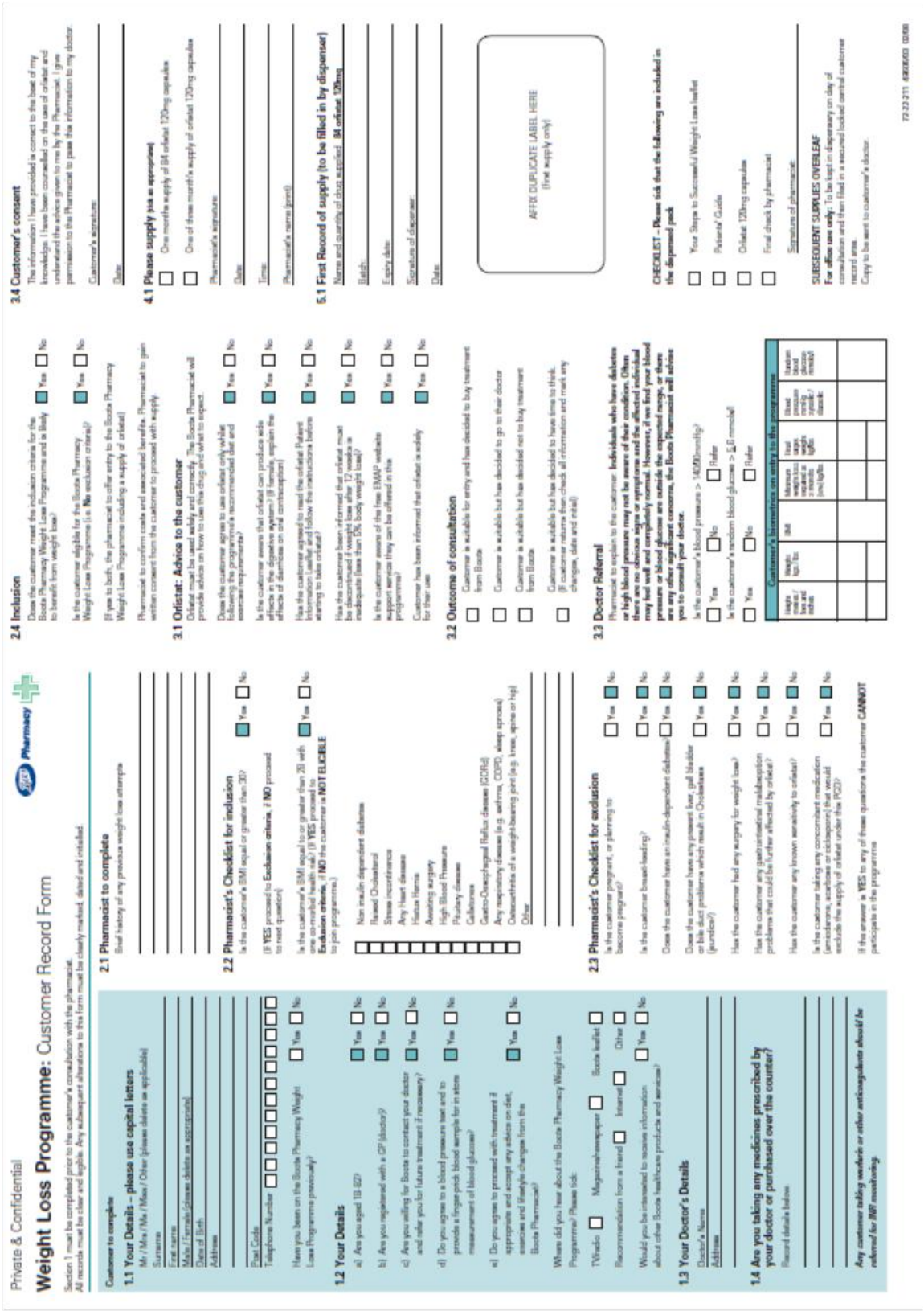
Approved X **Revise and Resubmit** ☐

Signed

Name Claire Anderson

Date -3-03-2011

Appendix 7 Four forms of BPWLP



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Pharmacy

Weight Loss Programme: Customer Record Form

Section 1 must be completed prior to the customer's consultation with the pharmacist.
All records must be clear and legible. Any subsequent alterations to this form must be clearly marked, dated and initialled.

Customer to complete

1.1 Your Details – please use capital letters

Mr / Mrs / Ms / Miss / Other (please delete as applicable)
Surname
First name
Male / Female (please delete as appropriate)
Date of Birth
Address

Post Code
Telephone Number

Have you been on the Boots Pharmacy Weight Loss Programme previously? Yes No

1.2 Your Details

a) Are you aged 18-65? Yes No
b) Are you registered with a GP (doctor)? Yes No
c) Are you willing for Boots to contact your doctor and refer you for future treatment if necessary? Yes No
d) Do you agree to a blood pressure test and to provide a finger prick blood sample for in store measurement of blood glucose? Yes No
e) Do you agree to proceed with treatment if appropriate and accept any advice on diet, exercise and lifestyle changes from the Boots Pharmacist? Yes No

Where did you hear about the Boots Pharmacy Weight Loss Programme? Please tick:

TV radio Magazine/newspaper Boots leaflet
Recommendation from a friend Internet Other
Would you be interested to receive information about other Boots healthcare products and services? Yes No

1.3 Your Doctor's Details

Doctor's Name
Address

1.4 Are you taking any medicines prescribed by your doctor or purchased over the counter?

Record details below

Any customer taking warfarin or other anticoagulants should be referred for INR monitoring

2.1 Pharmacist to complete

Brief history of any previous weight loss attempts

2.2 Pharmacist's Checklist for inclusion

Is the customer's BMI equal or greater than 30? Yes No

(If YES proceed to **Exclusion criteria**, if **NO** proceed to next question)

Is the customer's BMI equal to or greater than 28 with one co-morbid health risk? (If YES proceed to **Exclusion criteria**, if **NO** the customer is **NOT ELIGIBLE** to join programme.) Yes No

Non insulin dependent diabetes
Raised Cholesterol
Stress incontinence
Any Heart disease
Hiatus Hernia
Awaiting surgery
High Blood Pressure
Pituitary disease
Gallstones
Gastro-Oesophageal Reflux disease (GORd)
Any respiratory disease (e.g. asthma, COPD, sleep apnoea)
Osteoarthritis of a weight-bearing joint (e.g. knee, spine or hip)
Other

2.3 Pharmacist's Checklist for exclusion

Is the customer pregnant, or planning to become pregnant? Yes No
Is the customer breast-feeding? Yes No
Does the customer have an insulin-dependent diabetes? Yes No
Does the customer have any present bile, gall bladder or bile duct problems which result in Cholestasis (jaundice)? Yes No
Has the customer had any surgery for weight loss? Yes No
Has the customer any gastrointestinal malabsorption problems that could be further affected by orlistat? Yes No
Has the customer any known sensitivity to orlistat? Yes No
Is the customer taking any concomitant medication (amiodarone, acarbose or ciclosporin) that would exclude the supply of orlistat under the PGD? Yes No

If the answer is **YES** to any of these questions the customer **CANNOT** participate in the programme

2.4 Inclusion

Does the customer meet the inclusion criteria for the Boots Pharmacy Weight Loss Programme and is likely to benefit from weight loss? Yes No

Is the customer eligible for the Boots Pharmacy Weight Loss Programme (i.e. **No** exclusion criteria)? Yes No

(If yes to both, the pharmacist to offer entry to the Boots Pharmacy Weight Loss Programme including a supply of orlistat)

Pharmacist to confirm costs and associated benefits. Pharmacist to gain written consent from the customer to proceed with supply.

3.1 Orlistat: Advice to the customer

Orlistat must be used widely and correctly. The Boots Pharmacist will provide advice on how to use this drug and what to expect.

Does the customer agree to use orlistat only whilst following the programme's recommended diet and exercise requirements? Yes No

Is the customer aware that orlistat can produce side effects in the digestive system? (If 'Yes', explain the effects of diarrhoea on oral contraception) Yes No

Has the customer agreed to read the orlistat Patient Information Leaflet and follow the instructions before starting to take orlistat? Yes No

3.2 Outcome of consultation

Customer is a suitable for entry and has decided to buy treatment from Boots

Customer is a suitable but has decided to go to their doctor

Customer is a suitable but has decided not to buy treatment from Boots

Customer is a suitable but has decided to have time to think. (If customer returns then check all information and mark any changes, date and initial)

3.3 Doctor Referral

Pharmacist to explain to the customer: **Individuals who have diabetes or high blood pressure may not be aware of their condition. Often there are no obvious signs or symptoms and the affected individual may feel well and completely normal. However, if we find your blood pressure or blood glucose are outside the expected range, or there are any other significant concerns, the Boots Pharmacist will advise you to consult your doctor.**

Is the customer's blood pressure > 140/90 (mmHg)? Yes No Refer

Is the customer's random blood glucose > 5.6 mmol/l? Yes No Refer

Customer's biometrics on entry to the programme								
Height (metres / feet and inches)	Weight (st / lb / kg)	BMI	Maximum weight loss included in programme (stones / lbs / kgs)	Total steps / weight / BMI	Blood pressure (mmHg / mmHg / check)	Random blood glucose (mmol/l)	

3.4 Customer's consent

The information I have provided is correct to the best of my knowledge. I have been counselled on the uses of orlistat and understand the advice given to me by the Pharmacist. I give permission to the Pharmacist to pass this information to my doctor.

Customer's signature
Date

4.1 Please supply (tick as appropriate)

One months supply of 84 orlistat 120mg capsules
One of three month's supply of orlistat 120mg capsules

Pharmacist's signature
Date
Time
Pharmacist's name (print)

5.1 First Record of supply (to be filled in by dispenser)

Name and quantity of dose supplied: **84 orlistat 120mg**

Batch
Expiry date
Signature of dispenser
Date

AFFIX DUPLICATE LABEL HERE
(first supply only)

CHECKLIST – Please tick that the following are included in the dispensed pack

Your Steps to Successful Weight Loss leaflet
Patients' Guide
Orlistat 120mg capsules
Final check by pharmacist
Signature of pharmacist

SUBSEQUENT SUPPLIES OVERLEAF

For office use only: To be kept in dispensary on day of consultation and then filed in a secured locked central customer record area.
Copy to be sent to customer's doctor.

72-22-211 (0808)(0)

Figure A7.1 Customer record form

Private & Confidential

Weight Loss Programme: Repeat Supply Record

Pharmacy Weight Loss Programme

Date	Week	Name of Medicine	Quantity	Batch	Expiry	Dispenser's Signature	Pharmacist's Signature	Private Prescription Ref No/Comments
	0	orlistat 120mg						
	1	orlistat 120mg						
	2	orlistat 120mg						
	3	orlistat 120mg						
	4	orlistat 120mg						
	5	orlistat 120mg						
	6	orlistat 120mg						
	7	orlistat 120mg						
	8	orlistat 120mg						
	9	orlistat 120mg						
	10	orlistat 120mg						
	11	orlistat 120mg						
	12	orlistat 120mg						
	13	orlistat 120mg						
	14	orlistat 120mg						
	15	orlistat 120mg						
	16	orlistat 120mg						
	17	orlistat 120mg						
	18	orlistat 120mg						
	19	orlistat 120mg						
	20	orlistat 120mg						
	21	orlistat 120mg						
	22	orlistat 120mg						
	23	orlistat 120mg						
	24	orlistat 120mg						

1 **General progress**

Now weight, total weight loss to date, average weekly weight loss. (FLWP website support service). Acceptability of diet. Exercise achievement. Reinforcement of successes & achievements. Customer satisfaction with programme?

2 **Drug treatment review**

Orlistat compliance, treatment effects & side effects? (Remember a Yellow Card for any serious suspected adverse reactions)

3 **Any changes in general health or other medication**

(Is there a reason why the patient should stop treatment?) – see PGD 'Clinical situation for which medicine is to be used' & 'Criteria for exclusion'

4 **Reminder of weight targets –**

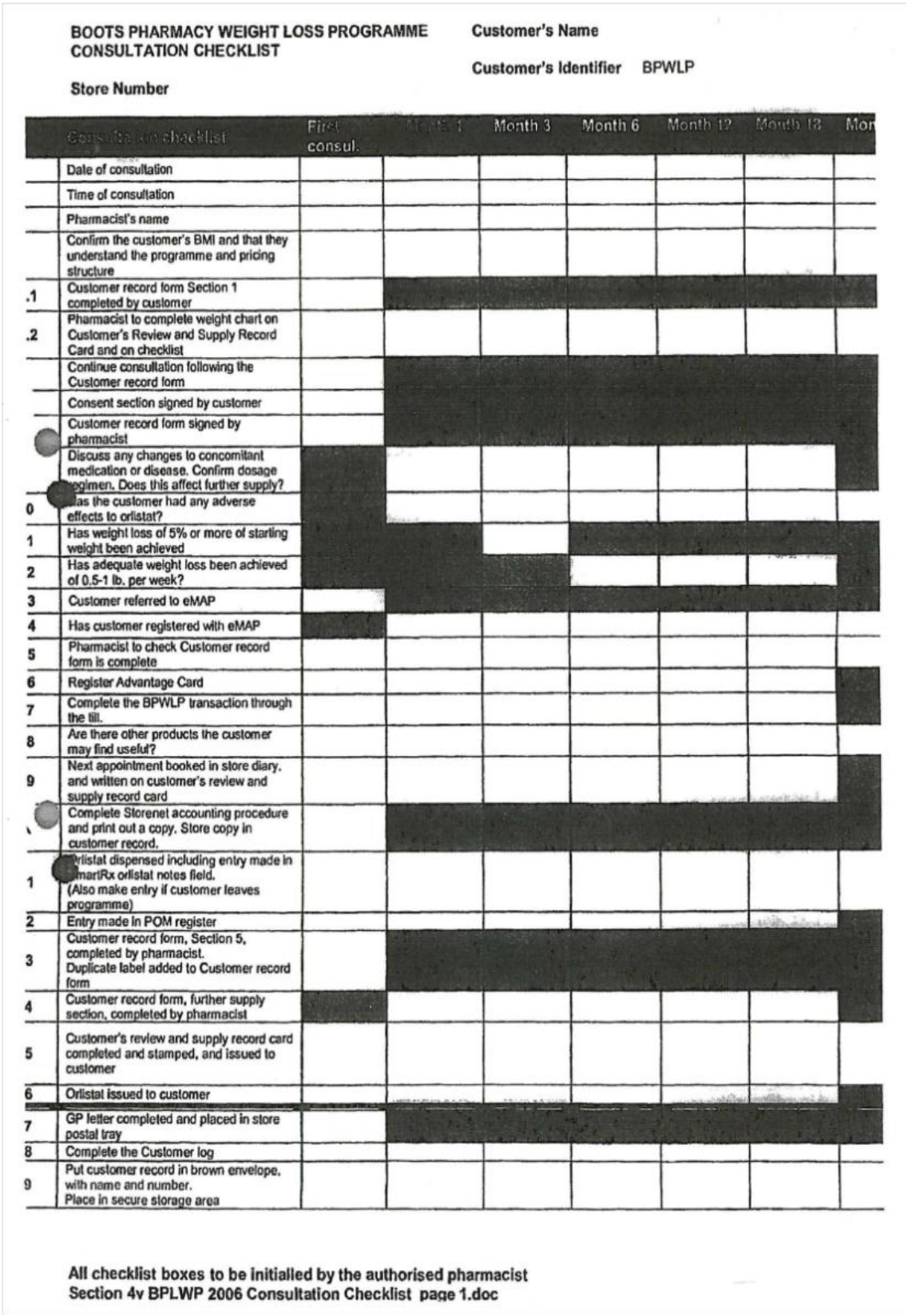
5% weight loss at 12 weeks. Typical 0.5-1 lb. weight loss per week, until treatment weight target.

5 **Next review appointment date.**

6 **Repeat orlistat supply arrangements including prices and discounts etc.**

7 **Any questions?**

Figure A7.2 Repeat supply record



BOOTS PHARMACY WEIGHT LOSS PROGRAMME
CONSULTATION CHECKLIST

Customer's Name

Customer's Identifier BPWLP

Store Number

	Consultation checklist	First consul.	Month 1	Month 3	Month 6	Month 12	Month 18	Mon
	Date of consultation							
	Time of consultation							
	Pharmacist's name							
	Confirm the customer's BMI and that they understand the programme and pricing structure							
.1	Customer record form Section 1 completed by customer							
.2	Pharmacist to complete weight chart on Customer's Review and Supply Record Card and on checklist							
	Continue consultation following the Customer record form							
	Consent section signed by customer							
	Customer record form signed by pharmacist							
	Discuss any changes to concomitant medication or disease. Confirm dosage regimen. Does this affect further supply?							
0	Has the customer had any adverse effects to orlistat?							
1	Has weight loss of 5% or more of starting weight been achieved							
2	Has adequate weight loss been achieved of 0.5-1 lb. per week?							
3	Customer referred to eMAP							
4	Has customer registered with eMAP							
5	Pharmacist to check Customer record form is complete							
6	Register Advantage Card							
7	Complete the BPWLP transaction through the till.							
8	Are there other products the customer may find useful?							
9	Next appointment booked in store diary, and written on customer's review and supply record card							
	Complete Storenet accounting procedure and print out a copy. Store copy in customer record.							
1	Orlistat dispensed including entry made in SmartRx orlistat notes field. (Also make entry if customer leaves programme)							
2	Entry made in POM register							
3	Customer record form, Section 5, completed by pharmacist. Duplicate label added to Customer record form							
4	Customer record form, further supply section, completed by pharmacist							
5	Customer's review and supply record card completed and stamped, and issued to customer							
6	Orlistat issued to customer							
7	GP letter completed and placed in store postal tray							
8	Complete the Customer log							
9	Put customer record in brown envelope, with name and number. Place in secure storage area							

All checklist boxes to be initialled by the authorised pharmacist
Section 4v BPLWP 2006 Consultation Checklist page 1.doc

Figure A7.3 Consultation checklist

Weight Loss Chart and Customer's Consultation Notes.

Review Stage / Date	Weight	BMI	Actual Weight Loss / Total Weight Loss	Min Weight Loss required	Notes
1st appoint.					
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					

REVIEWS in **bold** indicate when **mandatory** reviews are required and minimum weight loss targets must be achieved to continue with the PGD.

Section 4v BPWLP 2006 Consultation Checklist page2.doc

Figure A7.4 Weight loss chart and Customer's consultation notes

Appendix 8 Testing normal distribution

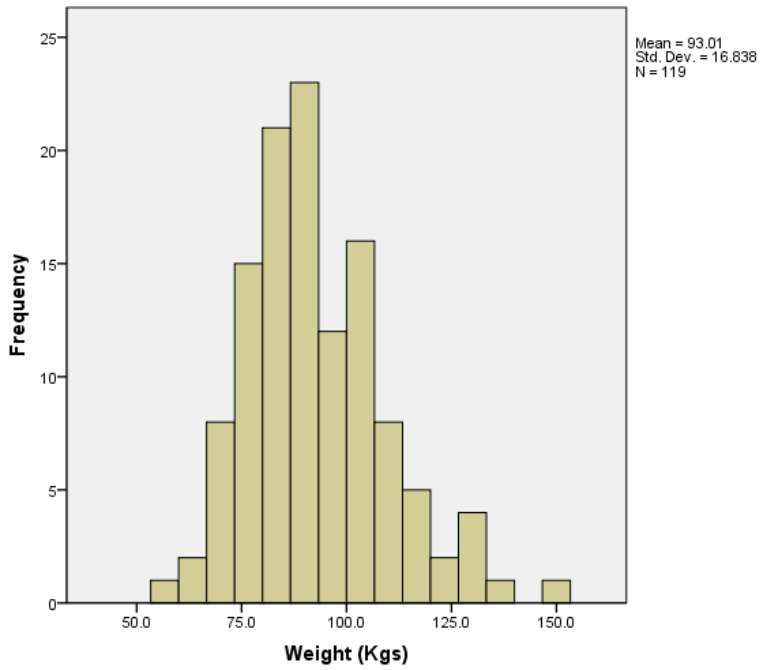


Figure A8.1 Tests of normality for weight data with Histograms

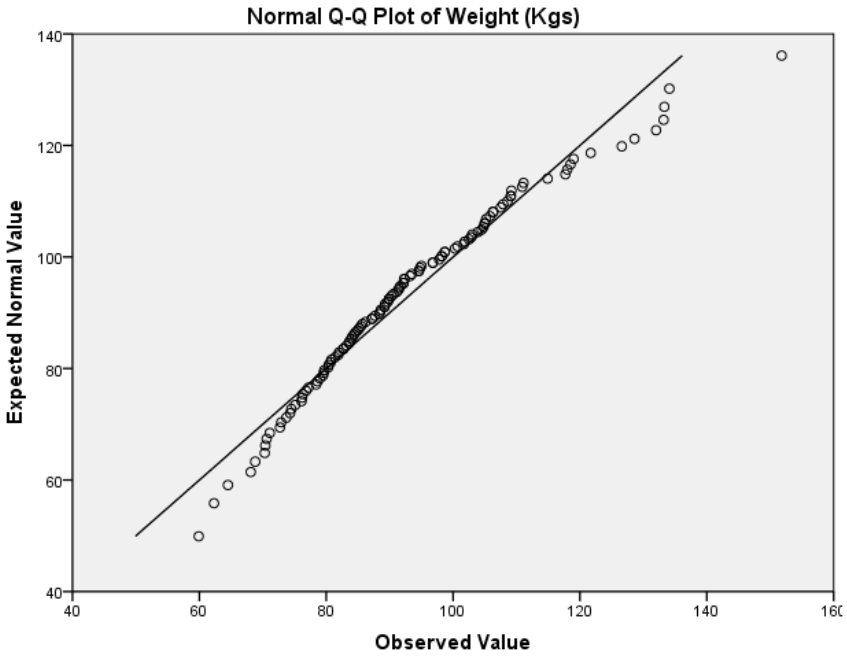


Figure A8.2 Tests of normality for weight data with Normal Q-Q Plot

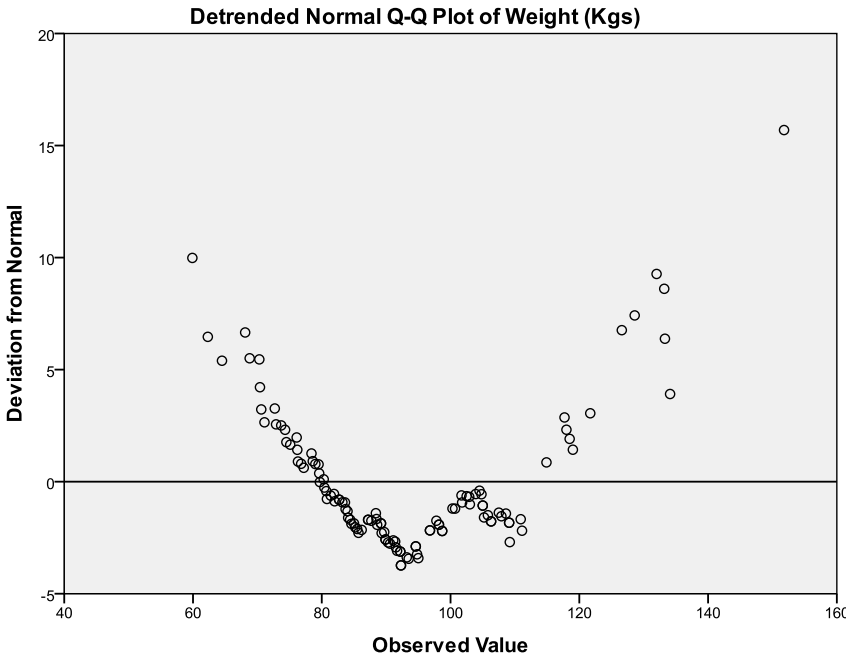


Figure A8.3 Tests of normality for weight data with Detrended Normal Q-Q Plots

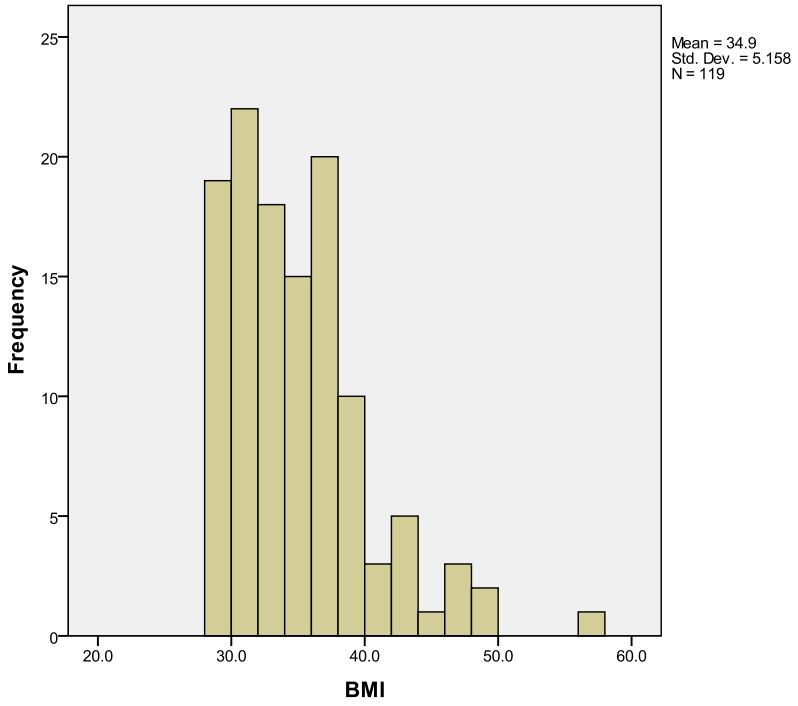


Figure A8.4 Tests of normality for BMI data with Histograms

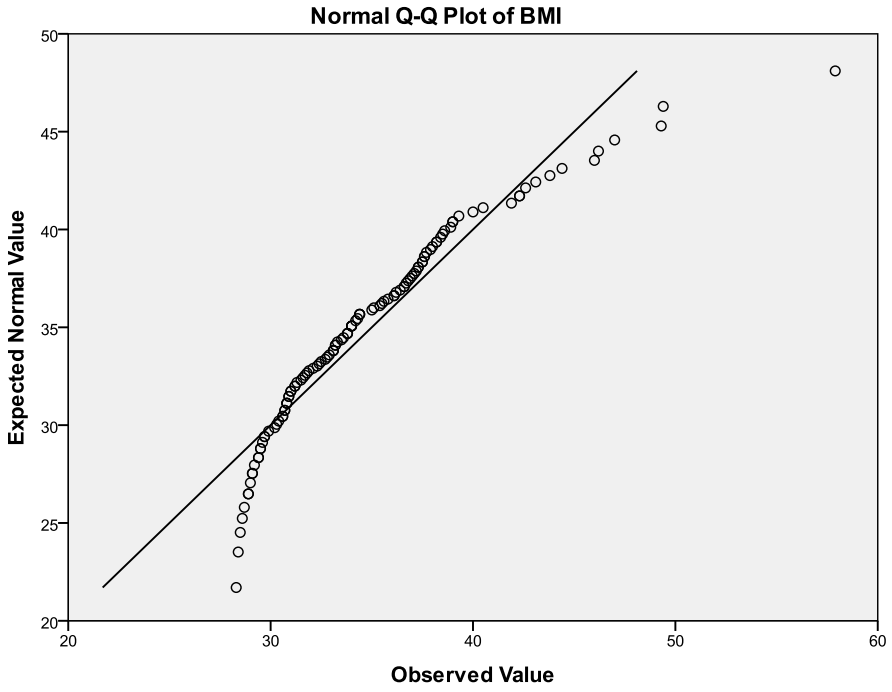


Figure A8.5 Tests of normality for BMI data with Normal Q-Q Plot

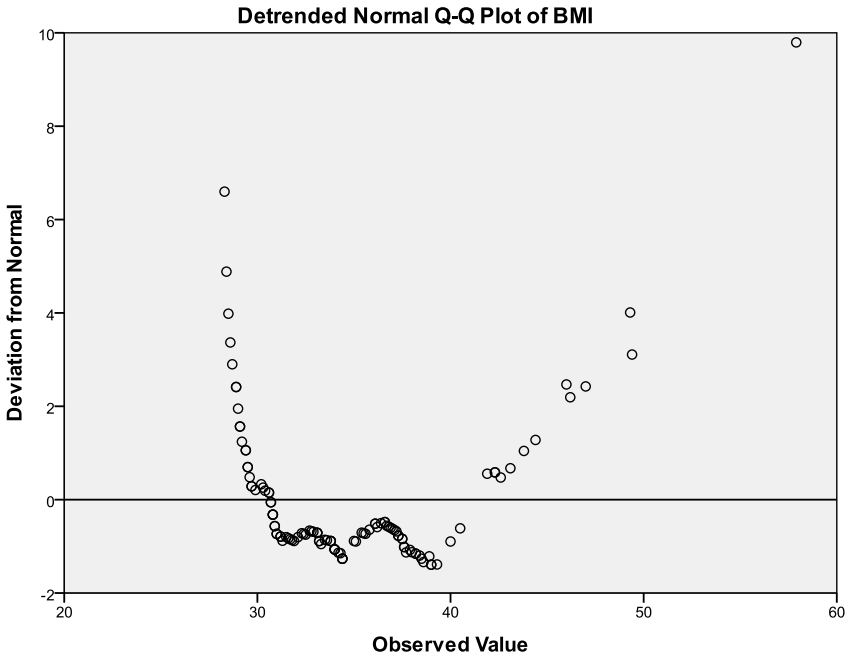


Figure A8.6 Tests of normality for BMI data with Detrended Normal Q-Q Plots

Appendix 9 Number of clients' visit and supply orlistat

Table A9.1 Number of visits and orlistat supply at the particular time point (n = 120)

Follow-up visit at	Attended for follow-up visits		Orlistat supply	
	n	%	n	%
1 month	116	17.0	116	20.8
2 months*	103	15.1	102	18.3
3 months	111	16.3	94	16.8
4 months*	98	14.4	51	9.1
5 months*	99	14.6	49	8.7
6 months	46	6.8	41	7.3
7 months*	27	4.0	27	4.8
8 months*	23	3.4	23	4.0
9 months	20	2.9	20	3.4
10 months*	10	1.5	10	1.8
11 months*	10	1.5	10	1.8
12 months	9	1.3	9	1.6
13 months*	1	0.15	1	0.2
14 months*	1	0.15	1	0.2
15 months	1	0.15	1	0.2
16 months*	1	0.15	1	0.2
17 months*	1	0.15	1	0.2
18 months	1	0.15	1	0.2
19 months*	1	0.15	1	0.2
20 months*	1	0.15	1	0.2
Total	680	100.0	559	100.0

*Clients purchasing three months supply of orlistat did not need to attend for these follow-ups.

Appendix 10 Agreement was extracted from the contract with Boots UK Limited

Schedule One – Description of Project

PROJECT TITLE: Weight management

Academic Supervisor: Dr Helen Boardman

Academic Co-supervisor: Prof Tony Avery

Industrial Supervisor: Julie Hanmer

This project aims to investigate weight management services and treatments primarily through an evaluation of a pharmacist-led weight management service where orlistat is supply via a Patient Group Direction (a private service provide by Boots).

The first phase of this study will evaluate the Boots Pharmacy Weight Loss Programme. The primary outcome for the study will be the weight loss and reduction in BMI achieved after three months in the programme. The study will also include a description of the clients who participate in the programme, determination of how long clients continue with the programme and description of factors which influence length of time in the programme.

Data will be collected from paper records held in Boots Pharmacies selected to include a range of locations. Data will be collected from the initial assessment visit and follow-up visits, and will include demographics, biometric measurements, details of the assessment of inclusion and exclusion critera, supplies of orlistat, dates of visits and comments about progress and side-effects.

Data analysis will consist of frequency counts with percentages to describe the data. Effectiveness of the service in reducing weight and BMI will be tested using paired t-tests and an evaluation of the clinical relevance of any changes.

Schedule Two Materials

Data collection

The Student shall not be given direct access to customer records held in store. To comply with the requirements of the Data Protection Act 1998, only anonymised copies of the paper records held in Boots Pharmacies (i.e. the customer record forms for customers treated under the Boots Pharmacy Weight Management programme) shall be provided to the Student. The records shall be collated by a Boots employee and all patient identifiers shall be blanked out prior to photocopying. A second check shall be carried out by another Boots employee to ensure that the photocopies are fully anonymised, before being provided to the Student.

Letters for data collectors

The University of Nottingham

School of Pharmacy
University Park (East Drive)
Nottingham
NG7 2RD
Tel +44 (0) 115 951 5051
Fax +44 (0) 115 951 5078
www.nottingham.ac.uk/pharmacy

Dear Pharmacist in charge,

I am a PhD student at the University of Nottingham and I am currently conducting research to evaluate the Boots Pharmacy Weight Loss Programme (BPWLP). The primary purpose of the study is to evaluate the effectiveness of a pharmacist-led weight management clinic in achieving weight loss in obese clients through a combination of orlistat supply and advice. I have permission from Boots Head Office to conduct this research and my contact there is Julie Hanmer, Tel: 0115 9495192, Julie.hanmer@boots.co.uk

My research involves recruiting Boots pharmacies where at least 20 clients have participated in the BPWLP before January 2009. The research involves collecting data recorded on store held customer record forms. These data will then be analysed to evaluate the service.

Your store has been selected as a store in the East Midlands area where at least 20 clients have used the service. Participating in the study would involve you allowing a named Boots employee access to the in-store records. They will collect anonymised data at your store for a few days.

Your pharmacy and clients' details will be kept confidential and be anonymised in the reports and publications arising from this study. I have received ethical approval from the School of Pharmacy, University of Nottingham. I have attached a summary of the planned research for your information. In the meantime, please do not hesitate to contact me if you have any queries. My contact details are below.

Yours faithfully,

Sukhumaphorn Sriwisit (Golf)
PhD Research Student
Division of Social Research in Medicines and Health, School of Pharmacy
University of Nottingham, Nottingham NG7 2RD
Mobile: 07827 525 531, Tel: 0115 95 15042 (Monday-Friday: 10.00-18.00)
E-mail: paxss7@nottingham.ac.uk

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The University of Nottingham

Evaluation of a pharmacist-led weight management clinic

Background
In England obesity has increased approximately 3-fold since 1980. Obesity guidelines recommend maintaining a healthy weight by balancing 'calories in' and 'calories out' and eating a healthy diet. If people are struggling to lose weight with lifestyle modification, pharmacological treatment should be considered. Orlistat, the most frequently prescribed medicine, has until recently only been available on prescription or via private patient group directions (PGD).

Aim
The aim of this project is to evaluate the effectiveness of a pharmacist-led weight management clinic consisting of lifestyle advice, weight monitoring and the supply of orlistat via PGD.

Method
A method involves retrospective record analysis. This project will evaluate the Boots Pharmacy Weight Loss Programme (BPWLP). The primary outcome for the study will be the weight loss and reduction in body mass index (BMI) achieved after three months in the programme. The project will also include a description of the clients who participate in the programme, determination of how long clients continue with the programme and description of factors which influence length of time in the programme.

Data will be collected from customer record forms held in Boots Pharmacies selected to include a range of locations. Data will be collected from the initial assessment visit and follow-up visits, and will include client demographics, biometric measurements, details of the assessment of inclusion and exclusion criteria, supplies of orlistat, dates of visits and comments about progress and side-effects.

All client data will be anonymised by a Boots employee accessing the records. Clients' names and addresses will not be made available to the researcher.

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13 May 2011

Dear Pharmacist in Charge

Boots Pharmacy Weight Loss Programme – data collection

Thank you for agreeing to assist with this research project. This letter is to introduce Sophia Salta who is a Boots employee carrying out data collection on behalf of the University of Nottingham. She will also present you with her staff discount card by way of identification.

If you have any queries about this study please do not hesitate to contact the researcher working on the project, Sukhumaphorn Sriwisit (Golf) (phone 0115 95 15042 or email paxss7@nottingham.ac.uk), or me, her academic supervisor (phone 0115 95 14291 or email helen.boardman@nottingham.ac.uk). Alternatively the Boots Head Office contact for the study is Julie Hanmer, phone 0115 9495192 or email julie.hanmer@boots.co.uk.

Yours sincerely

Dr Helen Boardman
Lecturer in Pharmacy Practice

Appendix 11 Data collection

Table A11.1 Completeness of data for blood pressure and blood glucose and doctor referral

Value of data set	Number of clients' BP and BG recorded	%
Blood pressure level recorded (mmHg, n = 545)*		
90/60 - 129/84 (normal BP-review 1 yr)	233	42.8
130/85 - 139/89 (normal upper range-accept but recommend view 1 yr)	114	21.0
≥ 140/89 for BPWLP (refer to GP-recheck 2 wks)	198	36.2
Completeness (n = 557)		
Both pharmacist checks and had BP values	507	91.0
No pharmacist checks but had BP values	38	6.8
Clients declined to be measured by pharmacists	12	2.2
Doctor referral (mmHg, n = 198)		
No referral although BP < 140/85	146	73.7
Refer to doctor if BP ≥ 140/85	30	15.2
Refer to doctor if SBP < 140, DBP > 89	16	8.1
Refer to doctor if SBP ≥ 140, DBP ≤ 89	6	3.0
Blood glucose level recorded (n = 524)		
< 5.6 mmol/L	306	58.4
≥ 5.6 mmol/L	218	41.6
Completeness (n = 557)		
Both pharmacist checks and had BG values	479	86.0
No pharmacist checks but had BG values	45	8.0
Clients declined to be measured by pharmacists	35	6.0
Doctor referral (mmol/L, n = 218)		
No referral although BG < 5.6	158	72.5
Refer to doctor if BG ≥ 5.6	60	27.5

*Level and action from BPWLP SOP's

Appendix 12 Medicines prescribed and purchased over the counter

Table A12.1 Name of medicines prescribed and purchased over the counter (n = 557 clients)

1. Medicines for obesity-related health risks (n)*	
Diuretics (38)	Bendrofluazide, Bendroflumethiazide (2.5, 5 mg), Furosemide 40 mg, Co-amiofruse 2.5 mg, Indapamide 2.5 mg
Anti-arrhythmic drugs (1)	Rythmodan, Flecainide
Beta-adrenoceptor blocking drugs (28)	Beta blockers, Atenolol 25 mg (Tenoretic), Propranolol, Pindolol, Metoprolol, Nebivolol, Sotalol
Hypertension and heart failure (73)	BP medicines, Doxazosin (1, 2 mg), Tamsulosin, Micadis, Co-tenidone Losartan (Cozarr), Irbesartan 150 mg (Aprovel), Candesartan (4, 8 mg), Valsartan 80 mg, Perindopril (Coversyl), Olmesartan 10 mg, Telmisartan 80 mg Lisinopril (Lisprinol), Ramipril 15 mg (Tritace), Enalapril 10 mg, Perindopril Methyldopa, Accuretic
Nitrates, calcium-channel blockers and other antianginal drugs (39)	Trinitrate, Isosorbide mononitrate, Glyceryl Trinitrate, Ikorel 10 mg Verapamil 120 mg, Diltiazem 180 mg Nifedipine (Adalat, Coracten), Nifedipine MR 60, Amlodipine 5 mg (Istin), Lacidipine (Motens)
Antiplatelet drugs (1)	Aspirin (75, 300 mg), Dipyridamole
Lipid-regulating drugs (44)	Statins, Atorvastatin (Lipitor 10, 40 mg), Crestor (Rosuvastatin 20 mg), Simvastatin (Ezatimibe 40 mg) Bezafibrate (Bezalip), Fenofibrate
Bronchodilators (87)	Asthma medications, Salbutamol (Ventolin), Salmeterol, Blue inhaler (Terbutaline/ Bricanyl), Combivent, Serevent, Spiriva inhaler, Ipratopium bromide

*Many clients had more than one medicine, prescribed or OTC.

Table A12.1 (continued)

1. Medicines for obesity-related health risks (continued)	
Cortocosteroids (9)	Flixotide accuhaler 100 mcg, Seratide inhaler, Becotide, Foradil inhaler Beconase, Beclazone 100, Becloforte, Beclomethasone (Beclazone, Qvar 50 inhaler), Singulair, Prednisolone Symbicort, Pulmicort inhaler (400 mg), Rhinocort nasal spray
Drugs used in diabetes (10)	Metformin 500 mg, Glicazide
Thyroid and antithyroids drugs (32)	Thyroid drug, Thyroxine (Levothyroxine 50, 175 mcg)
Drugs affecting bone metabolism (2)	Fosamax
Drugs for genitor-urinary disorders (2)	Trimethoprim, Tolterodine
Cytotoxic drugs (1)	Herceptin
Drugs used in rheumatic diseases and gout (8)	Diclofenac (Voltarol, Diclomax, Arthrotec Forte), Ibuprofen (400 mg), Naproxen, Arthrotec 75, Mefenamic acid Azathiopine, Glucosamine (and Chondroitin), Sulfasalazine, Methotrexate
Drugs used in neuromuscular disorders (1)	Methocarbamol
2. Vitamins (79)	Multivitamin, Vitamin (supplement), Evening primrose oil, Cod liver oil, Calcium tabs, Cholecalciferol tablets (Vitamin D, Adcal D3, Calcichew), Calcium and Vitamin D, Vitamin B complex, Vitamin A, C and E, Zinc, Magnesium and Calcium, Osteocare, Multibionta 50+, Ivonne supplement

Table A12.1 (continued)

3. Other medicines (n)*	
Sex hormone (46)	Hormone Replacement Therapy (HRT, Estrapak), Estraderm (25, 50 mcg), Premarin (625 mg), Propecia, Elleste solo 1 mg, Kliovance, Femodene, Evorel, Hormone patches, Avodart, Tibolone, Primera, Dianette, Femoston
Antibacterial drugs (13)	Antibiotics, Tetracycline 250 mg, Oxytetracycline, Minocycline 50 mg, Erythromycin
Anagesics (132)	Tramadol, Paracetamol (Panadol, Co-codamol, Kapake, Tylex, Solpadol), Solpadeine, Paracetamol/Dihydrocodeine (Co-dydramol, Remedeine), Paracodeine, Sumatriptan, Movelat gel, Migraleve, Paramax (Paracetamol and metoclopramide)
Drugs acting in nausea and vertigo (2)	Cinnarizine 15 mg, Betahistine 16 mg
Antihistamines, hyposensitisation and allergic emergencies (35)	Antihistamine, Cetirizine 10 mg, Piriton, Avomine, Loratadine (Claritin), Xyzal (Hay tablets), Telfast, Nizatidine, Desloratadine (Neoclarityn)
Hypnotics and anxiolytics (4)	Zopiclone 7.5 mg, Temazepam
Antidepressant drugs (42)	Fluoxetine (Prozac), Citalopram 20 mg (Cipramil), Sertraline (Zoloft, Lustral 50, 100 mg), Fluvoxamine 100 mg, Camcolit 400 mg, Cipralex 10 mg, Paroxetine, Venlafaxine (Effexor or Efexor), Mirtazapine, Escitalopram, Amitriptyline
Drugs used in psychoses and related disorders (2)	Loxapine 10 mg, Lithium carbonate
Anti-epileptic drugs (13)	Pregabalin, Carbamazepine 200 mg (Tegretol), Phenytoin, Mysoline, Frisium, Gabapentin, Trihexylphenidyl, Epilim 300 mg, Depakote 100 mg, Topiramate, Acetazolamide
Drugs used in parkinsonism and related disorders (1)	Mirapexin (For restless leg syndrome-RLS)
Anti-coagulant (2)	Warfarin (3, 6 mg)
Antispasmodics and other drugs altering gut motility (1)	Colpermin, Mebeverine 135 mg (Fybogel)
Antisecretory drugs and mucosal protectants (42)	Nexium 40 mg, Omeprazole, Buccastem, Lansoprazole, Rabeprazole (Pariet), Gaviscon, Ranitidine, Mesalazine, Pantoprazole (Protium 20 mg), Peptac

*Many clients had more than one medicine, prescribed or OTC.

Table A12.1 (continued)

3. Other medicines (continued)	
Acute diarrhoea (1)	Loperamide 2.5 mg
Laxatives (1)	Macrogols (Movicol)
Antifungal drugs (1)	Terbinafine
Contraceptives (30)	Contraceptive pill, Microgynon 30, Noriday, Logynon, Cerazette, OTC oral contraceptive, Yasmin, Depo injection, Mirena, Orthogynol, Ovranette
Sex hormones and hormone antagonists in malignant disease (1)	Arimidex
Nutrition and blood (6)	Iron tabs (Ferrous sulphate 200, 500 mg), Folic acid
Others (37)	Sage drops, Garlic capsule, Eye drops acute infection, Cider vinegar tablet, Adios, Kalms (Herbal sedative), Mineral supplement, Confit wiki (Preserved food), Nasal drops, Liquifilm tears, Omega 3-6-9, Star flower oil, Ymea, Red clover, Semper acne, Horse chestnut, Smoking patches, Pregnacare, Chinese medicines for weight loss, Cranberry caps, Fish oil, Tumeric, Potassium, Capsaicin cream, St John's wort, Q10, Ginko, Aloe vera juice
Medicines discontinued (1)	Reductil 10 mg

Table A12.2 Name of medicines prescribed and purchased over the counter for 74 clients with BMI < 30 kg/m^2

1. Medicines for obesity-related health risks (n)*	
Diuretics (2)	Bendrofluazide, Bendroflumethiazide (2.5 mg)
Beta-adrenoceptor blocking drugs (3)	Atenolol 25 mg (Tenoretic)
Hypertension and heart failure (8)	BP medicines, Losartan (Cozarr), Irbesartan 150 mg (Aprovel), Lisinopril (Lisprinol), Ramipril 15 mg (Tritace)
Nitrates, calcium-channel blockers and other antianginal drugs (1)	Nifedipine
Antiplatelet drugs (3)	Aspirin (75 mg)
Lipid-regulating drugs (6)	Crestor (Rosuvastatin 20 mg), Simvastatin (Ezatimibe 40 mg)
Bronchodilators (10)	Asthma medications, Salbutamol (Ventolin), Serevent, Spiriva inhaler
Cortocosteroids (6)	Seratide inhaler, Becotide, Becloforte, Beclomethasone (Qvar 50 inhaler), Prednisolone, Symbicort
Drugs used in diabetes (2)	Metformin 500 mg
Thyroid and antithyroids drugs (5)	Thyroid drug, Thyroxine (Levothyroxine 50, 175 mcg)
Drugs affecting bone metabolism (2)	Fosamax
Drugs used in rheumatic diseases and gout (11)	Diclofenac, Ibuprofen (400 mg), Glucosamine
2. Vitamins (7)	Multivitamin, Vitamin (supplement), Cod liver oil, Cholecalciferol tablets (Vitamin D, Adcal D3, Calcichew), Calcium and Vitamin D, Vitamin C

*Many clients had more than one medicine, prescribed or OTC.

Table A12.2 (continued)

3. Other medicines (n)*	
Sex hormone (7)	Hormone Replacement Therapy (HRT), Estraderm (25 mcg), Premarin (625 mg), Evorel
Antibacterial drugs (1)	Antibiotics
Anagesics (9)	Paracetamol (Panadol, Co-codamol), Paracetamol/Dihydrocodeine (Co-dydramol, Remedeine), Sumatriptan, Migraleve
Drugs acting in nausea and vertigo (2)	Cinnarizine 15 mg, Betahistine 16 mg
Antihistamines, hyposensitisation and allergic emergencies (6)	Antihistamine, Loratadine (Claritin), Nizatidine, Desloratadine (Neoclarityn)
Hypnotics and anxiolytics (1)	Zopiclone 7.5 mg
Antidepressant drugs (7)	Fluoxetine (Prozac), Citalopram 20 mg (Cipramil), Sertraline (Zoloft), Amitriptyline
Anti-epileptic drugs (1)	Gabapentin
Drugs used in parkinsonism and related disorders (1)	Mirapexin (For restless leg syndrome-RLS)
Antispasmodics and other drugs altering gut motility (1)	Colpermin, Mebeverine 135 mg (Fybogel)
Antisecretory drugs and mucosal protectants (8)	Nexium 40 mg, Omeprazole, Lansoprazole, Gaviscon, Peptac
Contraceptives (2)	Contraceptive pill, Orthogynol
Nutrition and blood (2)	Iron tabs (Ferrous sulphate 200, 500 mg)
Others (2)	Chinese medicines for weight loss, Tumeric

*Many clients had more than one medicine, prescribed or OTC.

Appendix 13 Client's visit and orlistat supply

Table A13.1 Number of visits and orlistat supply at the particular time point (n = 557)

Visit	Follow-up visit at	Attended for follow-up visits		Orlistat supply	
		n	%	n	%
2	1 month	468	41.0	444	55.7
3	2 months*	181	16.0	90	11.3
4	3 months	207	18.0	115	14.4
5	4 months*	72	6.3	36	4.5
6	5 months*	41	3.6	18	2.3
7	6 months	67	6.0	41	5.1
8	7 months*	25	2.2	10	1.3
9	8 months*	15	1.3	5	0.7
10	9 months	21	1.8	13	1.6
11	10 months*	8	0.7	5	0.7
12	11 months*	4	0.3	2	0.2
13	12 months	11	0.9	6	0.8
14	13 months*	3	0.3	-	-
15	14 months*	2	0.2	-	-
16	15 months	5	0.4	3	0.4
17	16 months*	1	0.1	1	0.1
18	17 months*	2	0.2	1	0.1
19	18 months	4	0.3	4	0.5
20	19 months*	1	0.1	1	0.1
21	20 months*	-	-	-	-
22	21 months	2	0.2	2	0.2
23	22 months*	-	-	-	-
24	23 months*	-	-	-	-
25	24 months	1	0.1	-	-
Total		1,141	100.0	797	100.0

*Clients purchasing three months supply of orlistat did not need to attend for these follow-ups.

Appendix 14 Testing normality for outcomes and characteristics data

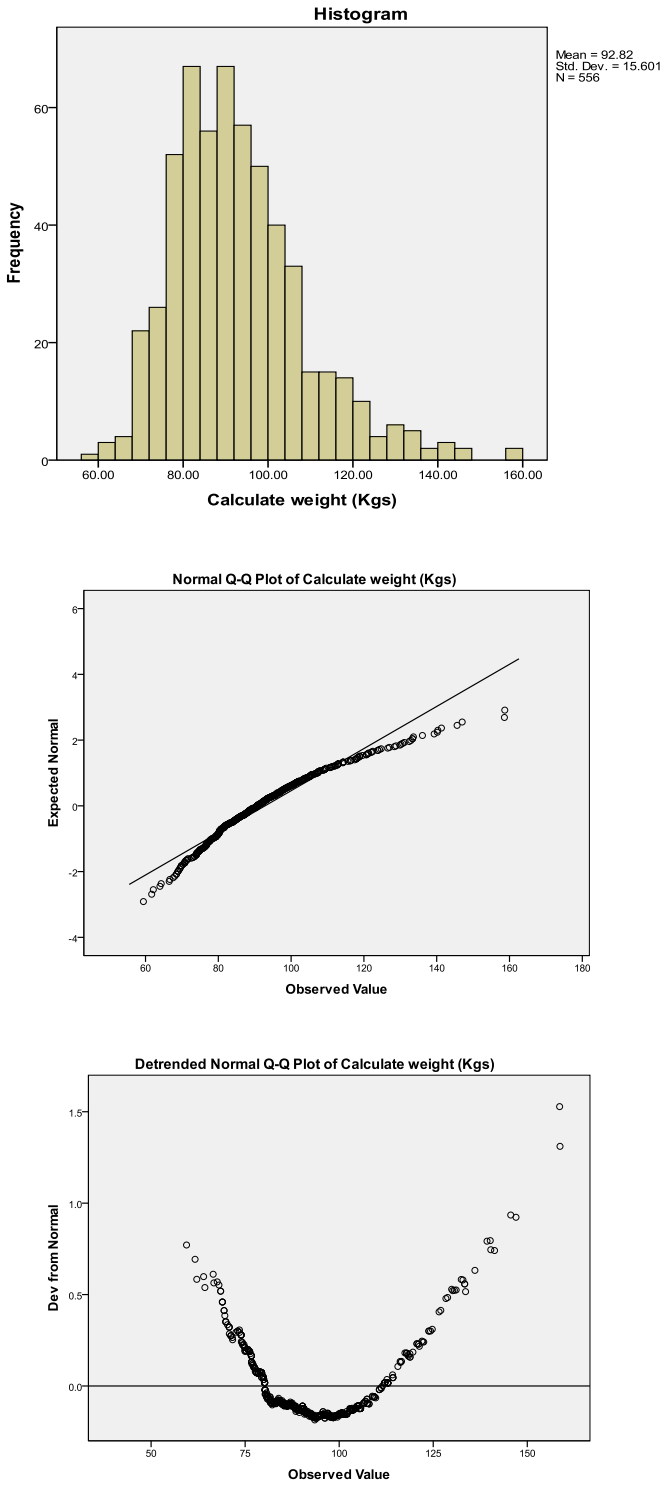


Figure A14.1 Tests of normality for weight data with Histograms, Normal Q-Q Plot and Detrended Normal Q-Q Plots

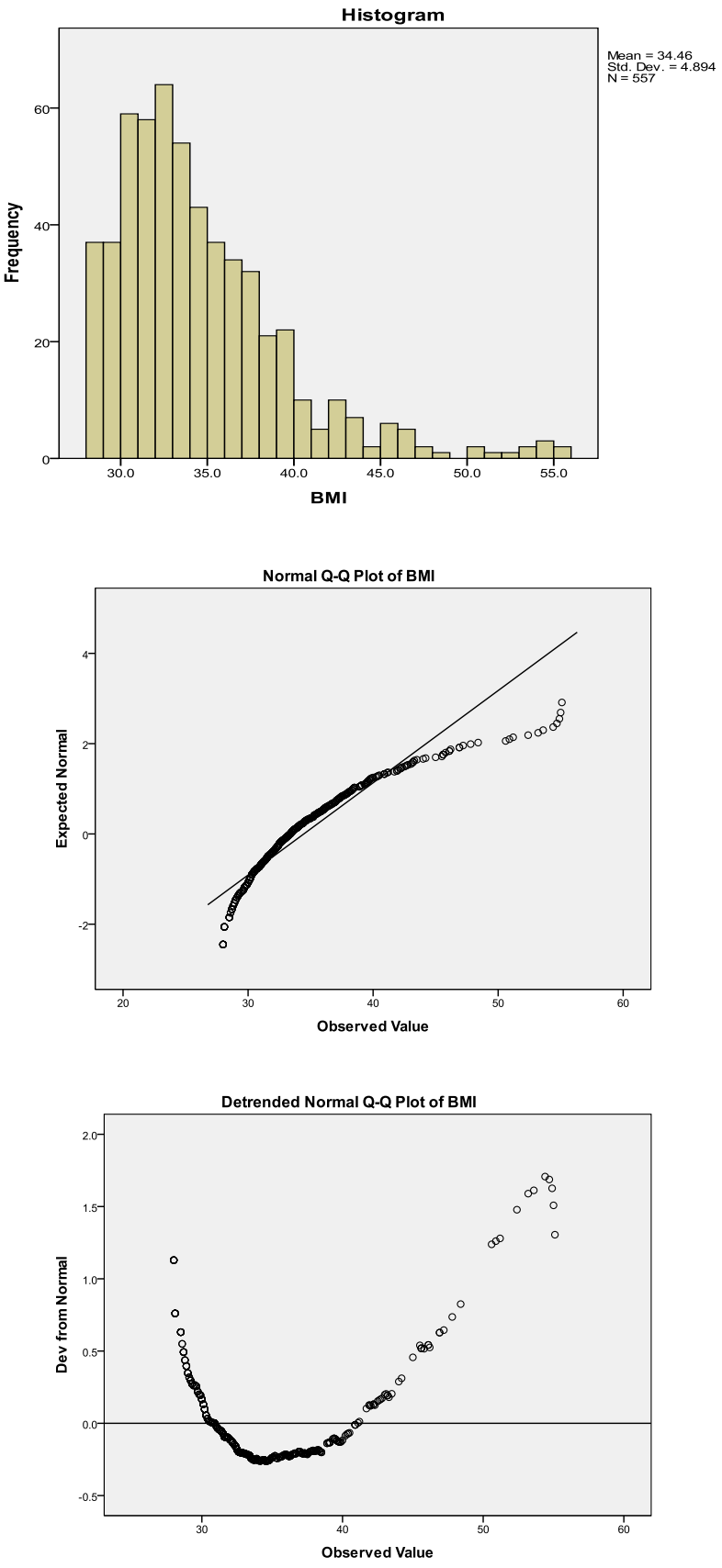


Figure A14.2 Tests of normality for BMI data with Histograms, Normal Q-Q Plot and Detrended Normal Q-Q Plots

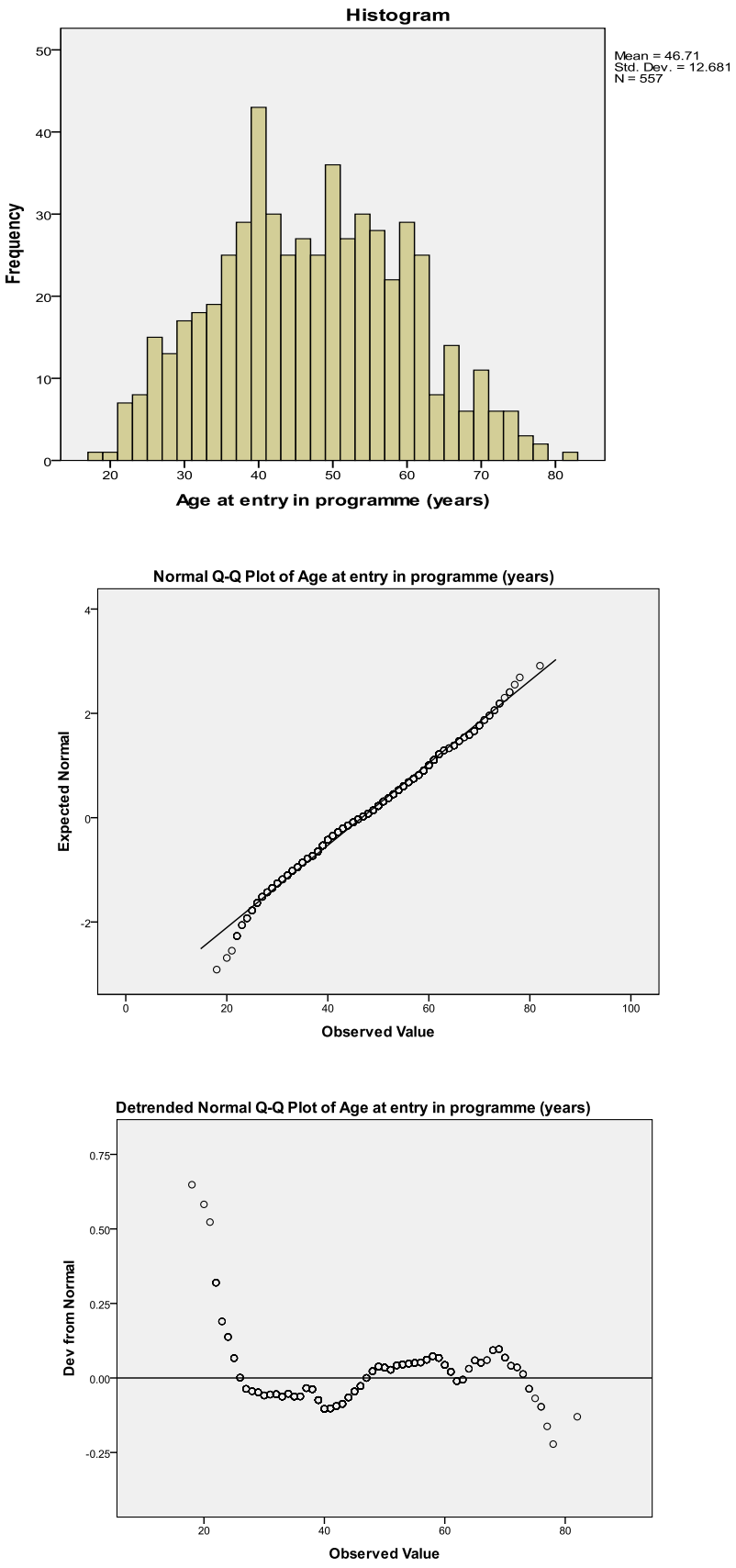
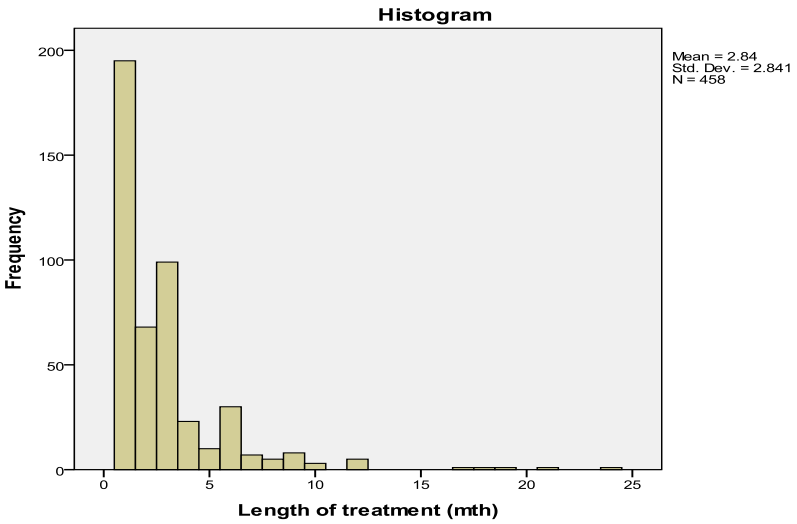
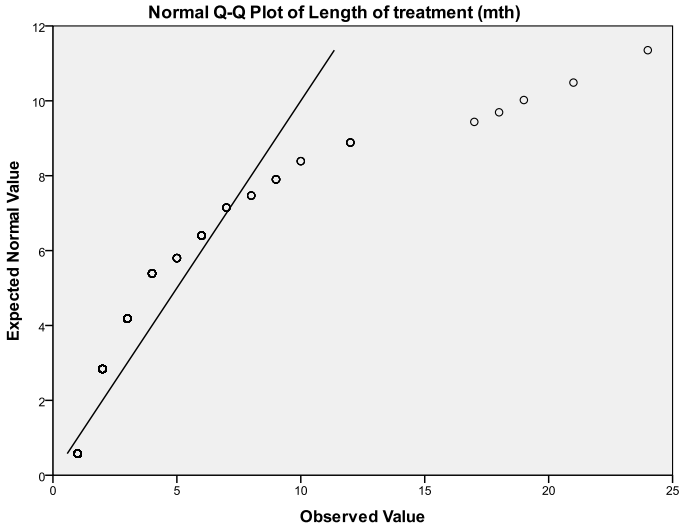


Figure A14.3 Tests of normality for age with Histograms, Q-Q plot and detrended normal Q-Q plots





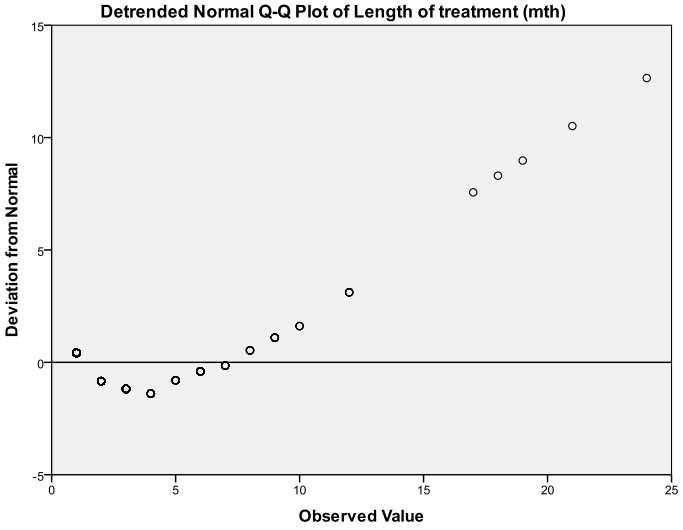


Figure A14.4 Tests of normality for length of treatment with Histograms, Q-Q plot and detrended normal Q-Q plots

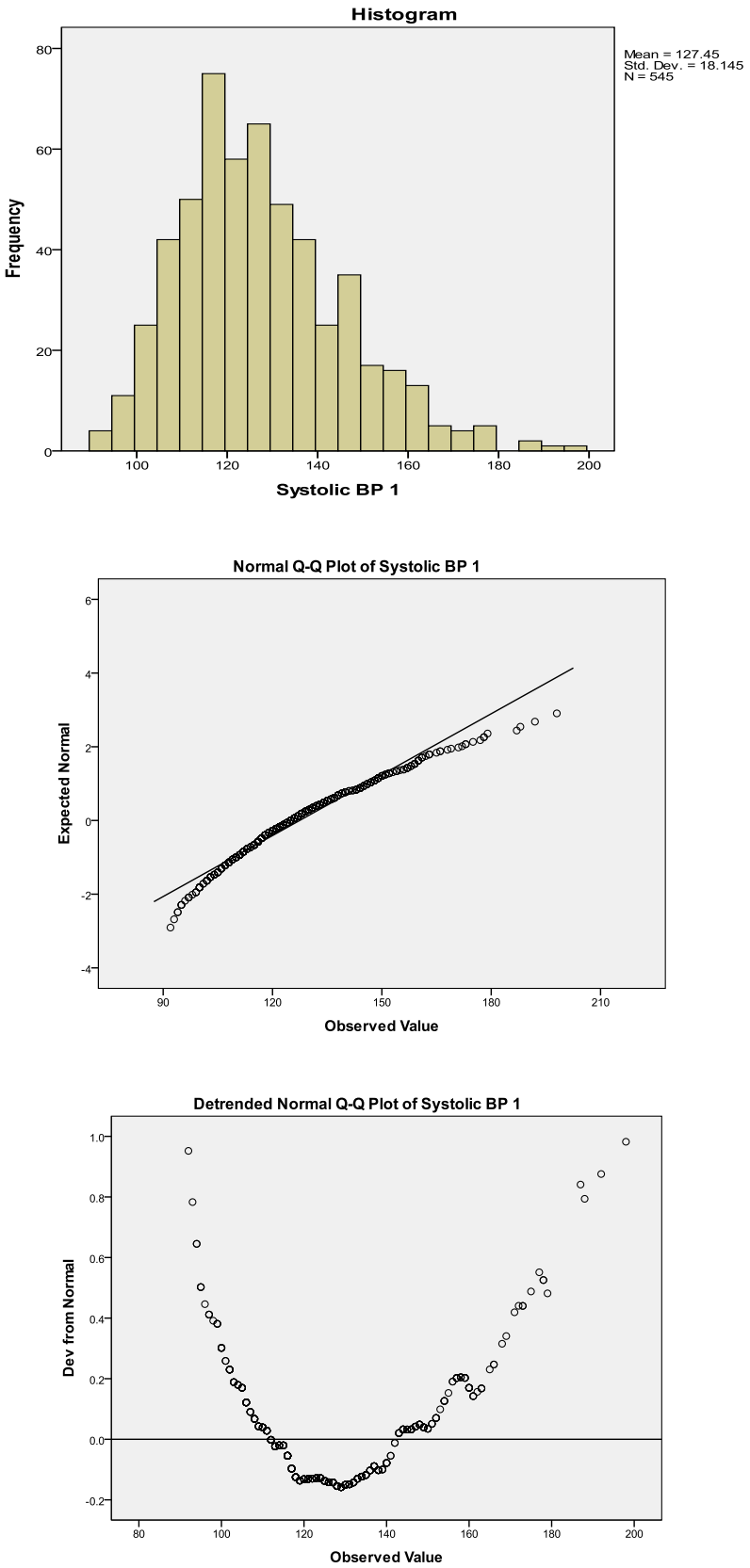


Figure A14.5 Tests of normality for systolic BP with Histograms, Q-Q plot and detrended normal Q-Q plots

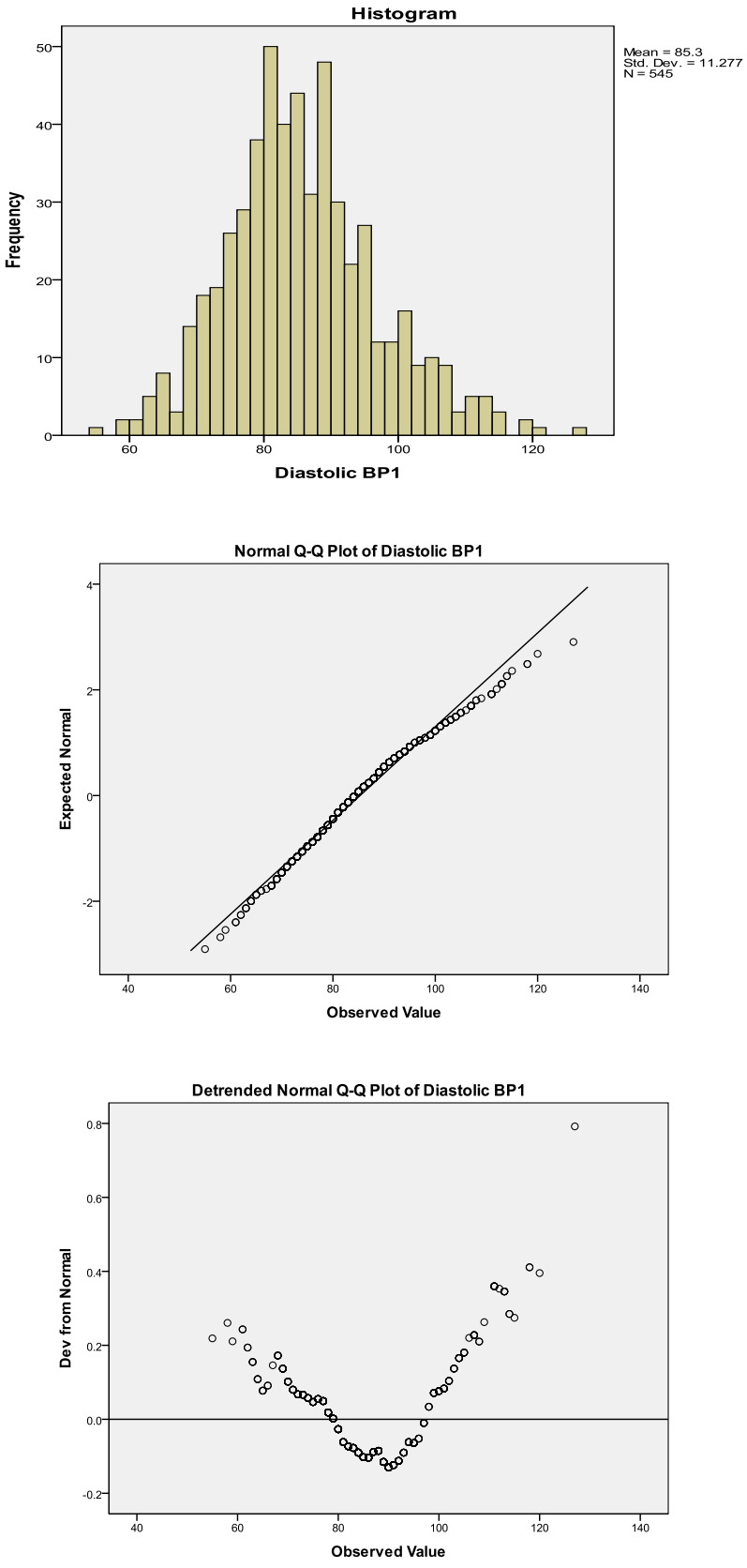


Figure A14.6 Tests of normality for diastolic BP with Histograms, Q-Q plot and detrended normal Q-Q plots

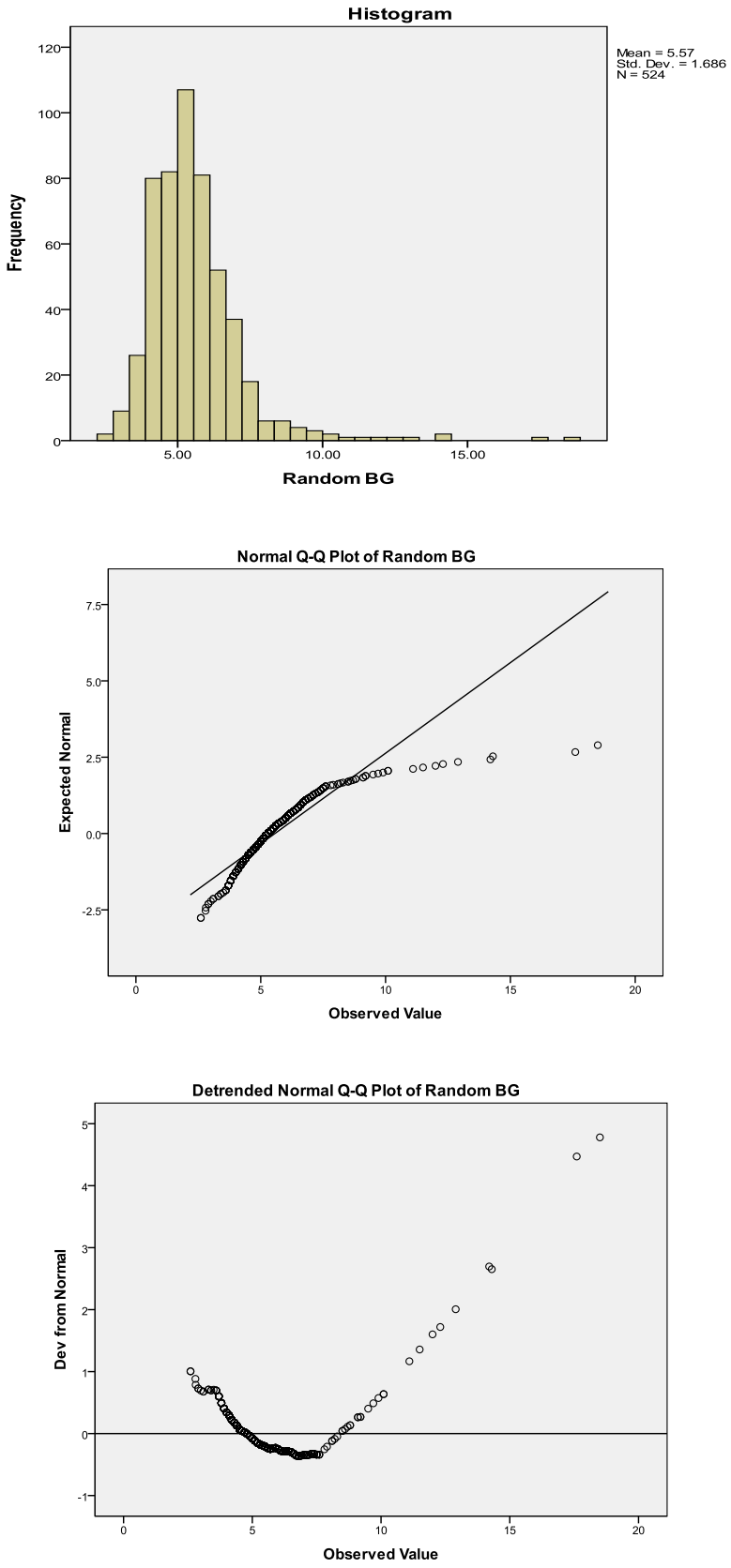


Figure A14.7 Tests of normality for random BG with Histograms, Q-Q plot and detrended normal Q-Q plots

Appendix 15 Customer questionnaire survey

Pre-test questionnaire

☐☐☐

The University of Nottingham

Your views of Boots Pharmacy Weight Loss Programme

Please remember that all responses will remain anonymous and confidential. Please tick ☑ all responses that apply to you.

Section 1: Experiences of the Boots Pharmacy Weight Loss Programme (BPWLP)

1. Where did you first hear about the Boots Pharmacy Weight Loss Programme?
   - Boots leaflet ❑ (1)
   - Internet ❑ (2)
   - Magazine ❑ (3)
   - Newspaper ❑ (4)
   - Radio ❑ (5)
   - Television ❑ (6)
   - Friends ❑ (7)
   - Health care professionals ❑ (8)
   - Other – please specify ❑ (9) .....

2. Why did you join the programme? Please choose all those that apply to you.
   - Concern about health ❑ (1)
   - To lose weight ❑ (2)
   - Make me happy ❑ (3)
   - Recommended by others – ❑ (4)
   - Please tell us who e.g. friend, relative, doctor, etc. .....
   - Other – please specify ❑ (5) .....

3. What was your weight at entry to this programme?

   ☐☐ stones and ☐☐ lbs or ☐☐☐ . ☐☐ kg

   Do not know/cannot remember ☐

4. How much weight were you targeted to lose at 3 months?

   ☐☐ stones and ☐☐ lbs or ☐☐☐ . ☐☐ kg

   Do not know/cannot remember ☐

5. How long is it since you joined the programme?
   - One month ❑ (1)
   - 2-3 months ❑ (2)
   - 4-6 months ❑ (3)
   - 7-12 months ❑ (4)
   - 13-24 months ❑ (5)
   - Other – please specify ❑ (6) ..... weeks/months

Page 1 [Please turn over…]

6. Whilst on the Boots Pharmacy Weight Loss Programme, do you consider that you have achieved your planned weight loss so far?

Yes	❑ (1)
No	❑ (2)
Not sure	❑ (3)

7. Please tell us about your medicine taken whilst on the programme.

I definitely take the medicine 3 times a day	❑ (1)
I only take the medicine when I cannot manage my diet	❑ (2)
I skip taking the medicine when I can manage my diet	❑ (3)
Other – please specify	❑ (4)

……

8. Please tell us about your diet whilst on the programme.

I have restricted my intake of calories and fat everyday	❑ (1)
I have nearly always managed to keep to my diet	❑ (2)
I have occasional days or meals where I struggle with the dietary restrictions	❑ (3)
I often cannot manage to keep to the diet	❑ (4)

9. Since starting the programme, my activity level is:

Less than usual	❑ (1)
About the same	❑ (2)
A little bit more	❑ (3)
A lot more	❑ (4)

10. Would you recommend the programme to others?

Yes	❑ (1)
No	❑ (2)
Not sure	❑ (3)

Please tell us why

Section 2: Experiences of the medicines (orlistat) and services received

Please read each statement and decide ☑ whether you strongly agree, agree, neither agree nor disagree, disagree, strongly disagree or not applicable (NA).

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	Not applicable
1. About the medicines received 1.1 I took the medicine as prescribed by the pharmacist.	❑	❑	❑	❑	❑	❑
1.2 I experienced side effects whilst taking the medicine.	❑	❑	❑	❑	❑	❑
1.3 I have been advised about orlistat use by a pharmacist.	❑	❑	❑	❑	❑	❑
1.4. I have understood how the medicine works whilst participating in this weight loss programme.	❑	❑	❑	❑	❑	❑
1.5 I am aware medicine can produce side effects in the digestive system.	❑	❑	❑	❑	❑	❑
1.6 I have read the medicine information leaflet.	❑	❑	❑	❑	❑	❑
1.7 I have followed instructions before starting to take orlistat.	❑	❑	❑	❑	❑	❑
1.8 I have only used this medicine whilst I am in the programme.	❑	❑	❑	❑	❑	❑
1.9 The pharmacist has informed about discontinuing the programme after 12 weeks if my weight loss is too little.	❑	❑	❑	❑	❑	❑
1.10 The pharmacist always asks me about how orlistat affects my everyday life.	❑	❑	❑	❑	❑	❑
1.11 I was not confident telling the pharmacist about my problems with orlistat.	❑	❑	❑	❑	❑	❑
1.12. I felt I did not receive enough information about orlistat from the pharmacist.	❑	❑	❑	❑	❑	❑

Section 2 continued: Please read each statement and decide ☑ whether you strongly agree, agree, neither agree nor disagree, disagree, strongly disagree or not applicable (NA).

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	Not applicable
2. About the services received 2.1 The consultation room made me feel comfortable.	❑	❑	❑	❑	❑	❑
2.2 I have been informed about how to succeed with weight loss.	❑	❑	❑	❑	❑	❑
2.3 I have discussed my weight with the pharmacist.	❑	❑	❑	❑	❑	❑
2.4 I am comfortable discussing my weight with the pharmacist.	❑	❑	❑	❑	❑	❑
2.5 I clearly understood how the programme works whilst participating in this weight loss programme.	❑	❑	❑	❑	❑	❑
2.6 I have received the best advice from the pharmacist.	❑	❑	❑	❑	❑	❑
2.7 The pharmacist has not provided advice properly.	❑	❑	❑	❑	❑	❑
2.8 The pharmacist fully explained the advantages of the programme.	❑	❑	❑	❑	❑	❑
2.9 The pharmacist was very careful to check everything before I joined the programme.	❑	❑	❑	❑	❑	❑
2.10 The pharmacist gave me every chance to talk about my weight problems.	❑	❑	❑	❑	❑	❑
2.11 The pharmacist helped to motivate me to try to lose weight.	❑	❑	❑	❑	❑	❑
2.12 The pharmacist asked about diets I have used during the programme.	❑	❑	❑	❑	❑	❑
2.13 The pharmacist asked about the exercise I did during the programme.	❑	❑	❑	❑	❑	❑
2.14 The pharmacist has been supportive.	❑	❑	❑	❑	❑	❑
2.15 This programme helped me set my weight target.	❑	❑	❑	❑	❑	❑

Section 2 continued: Please read each statement and decide ☑ whether you strongly agree, agree, neither agree nor disagree, disagree, strongly disagree or not applicable (NA).

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	Not applicable
2.16 This programme gave dietary advice.	❑	❑	❑	❑	❑	❑
2.17 This programme gave exercise recommendations.	❑	❑	❑	❑	❑	❑
2.18 This programme encouraged me to reach my optimal weight.	❑	❑	❑	❑	❑	❑
2.19 This programme offered the free electronic motivation, advice and proactive support (eMAP).	❑	❑	❑	❑	❑	❑
2.20 Overall, I have managed to keep my weight controlled since being in this programme.	❑	❑	❑	❑	❑	❑

3. Please tell us about what advantages you have received from this programme. Please choose all those that apply to you.

Content with the weight loss	❑ (1)
Reasonable cost	❑ (2)
Not complicated regimen	❑ (3)
Convenience travelling to stores	❑ (4)
Diet and exercise advice support	❑ (5)
Motivation support	❑ (6)
Online support	❑ (7)
Differed from other programmes	❑ (8)
Other – please specify	❑ (9)

Section 3: Experiences of other weight loss programmes and activities

Please tick ☑ all responses that apply to you. We are interested in your personal views so that there are no right or wrong answers.

1. What are the other types of your previous weight loss attempts?

Diet	❑ (1)
Exercise	❑ (2)
Meal replacement products	❑ (3)
- Atkins	❑ (3.1)
- Lipotrim	❑ (3.2)
- Slim Fast	❑ (3.3)
- Thermoslim (Fat burner)	❑ (3.4)
- Tony Ferguson	❑ (3.5)
Slimming clubs	❑ (4)
- Lighter life	❑ (4.1)
- Rosemary Connelly	❑ (4.2)
- Slimming World	❑ (4.3)
- Weight Watchers	❑ (4.4)
Weight loss tablets	❑ (5)
- Adios	❑ (5.1)
- Aquaban	❑ (5.2)
- Biosynergy Hoodia Gordonii	❑ (5.3)
- Holland & Barrett	❑ (5.4)
- LIPObind	❑ (5.5)
- Slim Nite	❑ (5.6)
- Zotrim (Herbal weight loss)	❑ (5.7)
Other - please specify	❑ (6) ……

2. If you have used diets, what types of diets have you tried?

Calorie counting/restriction	❑ (1)
Cutting down the amount of carbohydrates in my diet	❑ (2)
Cutting down the amount of fatty foods in my diet	❑ (3)
Daily food record	❑ (4)
Avoiding take away food	❑ (5)
Avoiding eating out at restaurants	❑ (6)
Eating more fruit and vegetables	❑ (7)
Eating smaller portions	❑ (8)
Missing meals	❑ (9)
Low GI (Glycaemia Index) diets	❑ (10)
Self-monitoring food intake	❑ (11)
Switching to low fat milk	❑ (12)
Limiting sweetened drinks/not adding sugar to drinks	❑ (13)
Other – please specify	❑ (14) ……

3. If you have used exercise to lose weight, what types of physical activity did you try?

Increase walking in my everyday life	❑ (1)
Cycling	❑ (2)
Swimming	❑ (3)
Low impact exercise classes	❑ (4)
- Aerobics/Aqua aerobics	❑ (4.1)
- Tai chi	❑ (4.2)
- Yoga	❑ (4.3)
High impact exercise classes	❑ (5)
- Step aerobics	❑ (5.1)
- Playing individual sports e.g. squash or tennis	❑ (5.2)
- Playing team sports e.g. netball, basketball or football	❑ (5.3)
Going to the gym	❑ (6)
Using stairs instead of a lift	❑ (7)
Other – please specify	❑ (8) .....

4. Please tell us which of the methods you have tried for weight loss:
   4.1 Easiest to do at the time

   .....
   .....

   4.2 Most successful in helping you lose weight

   .....
   .....

5. How has the Boots Pharmacy Weight Loss Programme compared with other methods you tried to lose weight? Please give any names of other methods you tried.

Section 4: About you

1. Are you? Male ❑ (1)
   Female ❑ (2)

2. What is your age?
   18-29 years ❑ (1)
   30-39 years ❑ (2)
   40-49 years ❑ (3)
   50-59 years ❑ (4)
   60-69 years ❑ (5)
   70 years and older ❑ (6)

3. Which of the following best describes your ethnic origin?
   White – British ❑ (1)
   White – Irish ❑ (2)
   Other White background ❑ (3)
   Black – British ❑ (4)
   Black Caribbean/African ❑ (5)
   Other Black background ❑ (6)
   Asian British – Indian/Pakistani/Bangladeshi ❑ (7)
   Other Asian background ❑ (8)
   Mixed White and Black Caribbean/African ❑ (9)
   Mixed White and Asian ❑ (10)
   Other Mixed background ❑ (11)
   Other Ethnic background ❑ (12)
   Prefer not to answer ❑ (13)

4. How would you describe your legal marital?
   Never married/Civil partnership ❑ (1)
   Married/Living as married ❑ (2)
   Separated, but still legally married/Civil partnership ❑ (3)
   Divorced/Civil partnership dissolved ❑ (4)
   Widowed/Civil partnership ❑ (5)
   Other – please specify ❑ (6) .....

5. How would you describe your education?
   I left school aged 16 years or younger and did no further education ❑ (1)
   I left school or college aged 17 or 18 years and did no further education ❑ (2)
   I did a further education qualification beyond the age of 18 years, but not a degree ❑ (3)
   I did an undergraduate degree ❑ (4)
   I did a postgraduate degree ❑ (5)
   Other – please specify ❑ (6)
   .....

6. Which of these activities best describes what you are doing at present?

Unemployed	❑ (1)
Employed in part-time (under 30 hours per week)	❑ (2)
Employed in full-time (30 hours plus per week)	❑ (3)
Self employed full or part time	❑ (4)
Full-time education at school, college or university	❑ (5)
Wholly retired from work	❑ (6)
Looking after the home/dependents	❑ (7)
Doing something else- please specify	❑ (8) .....

7. In which category does your family annual income fit best?

Under £20,000	❑ (1)
£20,000 - £39,999	❑ (2)
£40,000 - £59,999	❑ (3)
£60,000 - £79,999	❑ (4)
£80,000 and more	❑ (5)

8. How tall are you?

☐ feet ☐☐ inches or ☐.☐☐ metres

Do not know ☐

9. What is your weight at the moment?

☐☐ stones ☐☐ lbs or ☐☐☐ . ☐☐ kg

Do not know ☐

10. Are you currently under a doctor's care for a long term condition?

Yes (Please go to the next question)	❑ (1)
No (You have now finished the questionnaire – Thank you)	❑ (2)

11. Please indicate ☑ the following items that are about your health status. We are currently interested in your personal health status. (Please choose all those that apply to you.)

Coronary heart disease	❑ (1)
Circulatory disorder e.g. High blood pressure, High cholesterol, Stroke, Transient ischemic attack (TIA, mini stroke)	❑ (2)
Non insulin dependent diabetes mellitus (NIDDM)	❑ (3)
Osteoarthritis of a weight-bearing joint e.g. knee, spine, hip	❑ (4)
Any respiratory disease e.g. asthma, COPD, sleep apnoea	❑ (5)
Other – please specify	❑ (6)

.....

Thank you for your participation

Note: Please return your completed questionnaire in the reply paid envelope provided. A reminder will be sent to non-respondents.

Post-test questionnaire booklet

Your views of the Boots Pharmacy Weight Loss Programme

We are interested in your personal views of the Boots Pharmacy Weight Loss Programme. There are no right or wrong answers. Please help us by taking the time to answer this questionnaire. Your answers are very important.

This questionnaire will take 5 to 10 minutes to complete. All responses will remain anonymous and confidential to the research team.

3 May 2011

Sukhumaphorn Sriwisit, Helen Boardman, Tony Avery
School of Pharmacy
University of Nottingham

Please tick ☑ in the appropriate boxes or write the answer in the space provided.

Section 1: Experiences of the Boots Pharmacy Weight Loss Programme

1. Where did you first hear about the Boots Pharmacy Weight Loss Programme? Tick one box only.

Boots leaflet	❑
Internet	❑
Magazine	❑
Newspaper	❑
Radio	❑
Television	❑
Friends	❑
Pharmacists	❑
Health care professionals e.g. GP or dietician	❑
Other – please specify	❑

.....

2. Why did you join the Boots Pharmacy Weight Loss Programme? Tick all that apply to you.

I was concerned about my health	❑
I wanted to lose weight	❑
I wanted to make myself happy	❑
It was recommended by someone else Please tell us who e.g. friend, relative, doctor, etc.	❑
Other – please specify in the box below	❑

3. How long have you been in the Boots Pharmacy Weight Loss Programme? Tick one box only.

1 month	❑
2-3 months	❑
4-6 months	❑
7-12 months	❑
13-24 months	❑
Other – please specify	❑

..... weeks/months

4. What was your weight when you started the Boots Pharmacy Weight Loss Programme? Write number in box.

e.g. | 1 | 4 | st and | 1 | 2 | lbs

or | 1 | 0 | 5 | . | 4 | | kg

		st and			lbs	
or						kg

Don't know/can't remember ☐

5. What was your 3-month target weight loss?

		st and			lbs	
or						kg

Don't know/can't remember ☐

6. At present, have you achieved your target weight loss within the Boots Pharmacy Weight Loss Programme? Tick one box only.

Yes	❑
No	❑
Not sure	❑
Not enough time to achieve it	❑

7. Please tell us about your diet whilst on the Boots Pharmacy Weight Loss Programme. Tick one box only.

I have consistently kept strictly to my diet	❑
I have nearly always kept to the diet but there have been exceptional lapses	❑
I have mostly kept to the diet but with repeated lapses	❑
I have rarely managed to keep to my diet	❑

8. Since starting the Boots Pharmacy Weight Loss Programme, my activity level is..... Tick one box only.

Less than usual	❑
About the same	❑
A little bit more	❑
A lot more	❑

Please continue on the next page

Section 2: Experiences of the medicine (Orlistat 120 mg or Xenical ®)

Please read each statement about your medicine (orlistat) and indicate how much agree or disagree with each statement by placing a tick ☑ in the appropriate box. If a statement does not apply to you please indicate this by ticking the not applicable (NA) option.

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	Not applicable
1. I take the medicine as prescribed by the pharmacist.	❑	❑	❑	❑	❑	❑
2. I have got enough advice about the medicine from the pharmacist.	❑	❑	❑	❑	❑	❑
3. I understand how the medicine works whilst participating in this weight loss programme.	❑	❑	❑	❑	❑	❑
4. I have gained a better understanding about the medicine from reading the patient information leaflet.	❑	❑	❑	❑	❑	❑
5. I follow the instructions given about the medicine.	❑	❑	❑	❑	❑	❑
6. I felt I received enough information about the medicine from the pharmacist.	❑	❑	❑	❑	❑	❑
7. I tell the pharmacist about any problems with the medicine.	❑	❑	❑	❑	❑	❑
8. I have experienced side effects whilst taking the medicine.	❑	❑	❑	❑	❑	❑
9. I am aware that the medicine can upset my stomach.	❑	❑	❑	❑	❑	❑
10. I worry that the programme will be discontinued after 12 weeks if my weight loss is too little.	❑	❑	❑	❑	❑	❑
11. The pharmacist asks me about how the medicine affects my everyday life.	❑	❑	❑	❑	❑	❑

Section 3: Experiences of the weight loss service

Please read each statement of the weight loss service and indicate how much you agree or disagree with each statement by placing a tick ☑ in the appropriate box. If a statement does not apply to you please indicate this by ticking the not applicable (NA) option.

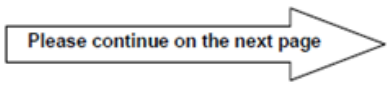
	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	Not applicable
1. About facilities						
1a. Travelling to the store is convenient.	❑	❑	❑	❑	❑	❑
1b. The consultation environment is comfortable.	❑	❑	❑	❑	❑	❑
1c. The cost of the weight loss programme is reasonable.	❑	❑	❑	❑	❑	❑

Please continue on the next page

Section 3: Experiences of the weight loss service (continued)

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	Not applicable
2. About service received						
2a. I feel that the information pharmacist provided has been useful for me to succeed with weight loss.	❑	❑	❑	❑	❑	❑
2b. I have a clear understanding of how the weight loss programme works.	❑	❑	❑	❑	❑	❑
2c. I have received advice about my weight loss from the pharmacist.	❑	❑	❑	❑	❑	❑
2d. The pharmacist makes me clear when discussing weight issues.	❑	❑	❑	❑	❑	❑
2e. The pharmacist has been a useful source of addition information about weight loss.	❑	❑	❑	❑	❑	❑
2f. The pharmacist helped to motivate me to try to lose weight.	❑	❑	❑	❑	❑	❑
2g. The pharmacist asked about diets I have used during the programme.	❑	❑	❑	❑	❑	❑
2h. Without the support from the pharmacist in the weight loss programme, I would not be able to manage my diet.	❑	❑	❑	❑	❑	❑
2i. The pharmacist asked about the exercise I did during the programme.	❑	❑	❑	❑	❑	❑
2j. Without the support from the pharmacist in the weight loss programme, I would not be able to manage my exercise.	❑	❑	❑	❑	❑	❑
2k. The pharmacist fully explained the advantages of weight loss.	❑	❑	❑	❑	❑	❑
2l. I feel I am managing to keep my weight controlled since being in the weight loss programme.	❑	❑	❑	❑	❑	❑
2m. I feel I am achieving my objectives of being in the weight loss programme.	❑	❑	❑	❑	❑	❑

Please tell us what you consider to be the advantages of this weight loss programme.



Section 4: Experiences of other weight loss programmes and activities

1. Please tell us which of the methods, programmes or products that you have previously tried for weight loss… Tick all that apply to you.

- Diet ❑
- Exercise ❑
- Meal replacement products ❑
  - Atkins ❑
  - Lipotrim ❑
  - Slim Fast ❑
  - Thermoslim (Fat burner) ❑
  - Tony Ferguson ❑
  - Other - please specify ❑ .....
- Slimming clubs ❑
  - Lighter life ❑
  - Rosemary Connelly ❑
  - Slimming World ❑
  - Weight Watchers ❑
  - Other - please specify ❑ .....
- Weight loss tablets ❑
  - Adios ❑
  - Aquaban ❑
  - Biosynergy Hoodia Gordonii ❑
  - Holland & Barrett ❑
  - LIPObind ❑
  - Slim Nite ❑
  - Zotrim (Herbal weight loss) ❑
  - Other - please specify ❑ .....
- Other - please specify ❑

.....

Out of the methods you have had above, please tell us which of the methods you have tried for weight loss:

Easiest to do at the time

Most successful in helping you lose weight

2. Which of the diet methods that you have previously tried for weight loss were… Tick all that apply to you.

- Calorie counting/restriction ❑
- Cutting down the amount of carbohydrates in my diet ❑
- Cutting down the amount of fatty foods in my diet ❑
- Daily food record ❑
- Avoiding take away food ❑
- Avoiding eating out at restaurants ❑
- Eating more fruit and vegetables ❑
- Eating smaller portions ❑
- Missing meals ❑
- Low GI (Glycaemia Index) diets ❑
- Self-monitoring food intake ❑
- Limiting sweetened drinks/not adding sugar to drinks ❑
- Other – please specify ❑

.....

Which of the above diet methods you have tried for weight loss:

Easiest to do at the time

Most successful in helping you lose weight

3. Which of the exercise methods that you have previously tried for weight loss were… Tick all that apply to you.

- Increase walking in my everyday life ❑
- Cycling ❑
- Swimming ❑
- Low impact exercise classes ❑
  - Aerobics/Aqua aerobics ❑
  - Tai chi ❑
  - Yoga ❑
  - Other - please specify ❑ .....
- High impact exercise classes ❑
  - Step aerobics ❑

Please continue on the next page

- Playing individual sports e.g. squash or tennis ❑
- Playing team sports e.g. netball, basketball or football ❑
- Other - please specify ❑

.....

Going to the gym ❑
Using stairs instead of a lift ❑
Other - please specify ❑

.....

Which of the above exercise methods you have tried for weight loss were…

Easiest to do at the time

Most successful in helping you lose weight

4. Would you recommend the Boots Pharmacy Weight Loss Programme to others? Tick one box only.

Yes ❑
No ❑
Not sure ❑

Please tell us why in the box below.

Section 5: About you

1. Are you? Tick one box only.

Male ❑
Female ❑

2. What is your age? Tick one box only.

18-29 years ❑
30-39 years ❑
40-49 years ❑
50-59 years ❑
60-69 years ❑
70 years and older ❑

3. Which of the following best describes your ethnic origin? Tick one box only.

White – British ❑
White – Irish ❑
Other White background ❑
Black – British ❑
Black Caribbean/African ❑
Other Black background ❑
Asian British – Indian/Pakistani/Bangladeshi ❑
Mixed White and Black Caribbean/African ❑
Mixed White and Asian ❑
Other Mixed background ❑

.....

Other Ethnic background ❑

.....

Prefer not to answer ❑

4. How would you describe your legal marital status? Tick one box only.

Never married ❑
Married/Living as married ❑
Separated, but still legally married ❑
Divorced ❑
Widowed ❑
Other – please specify ❑

.....

5. How would you describe your education? Tick one box only.

I left school aged 16 years or younger and did no further education ❑
I left school or college aged 17 or 18 years and did no further education ❑
I did further education qualification beyond the age of 18 years, but not ❑

Please continue on the next page

a degree
I did an undergraduate degree ❑
I did a postgraduate degree ❑
Other – please specify ❑

.....

6. Which of these activities best describes what you are doing at present? Tick all that apply to you.

Unemployed ❑
Employed part-time (under 30 hours per week) ❑
Employed full-time (30 hours plus per week) ❑
Self employed full time ❑
Self employed part time ❑
Full-time education at college or university ❑
Part-time education at college or university ❑
Wholly retired from work ❑
Looking after the home/dependents ❑
Doing something else - please specify ❑

.....

7. Please indicate in which one of the following categories your average annual household income (before tax and including all benefits) fits. Tick one box only.

£10,000 or under ❑
£10,001 - £30,000 ❑
£30,001 - £50,000 ❑
£50,001 - £70,000 ❑
£70,001 or more ❑
Prefer not to answer ❑

8. How tall are you? Write number in box.

e.g. [5] feet [1][0] inches

or [1][.][6][5] metres

[ ] feet [ ][ ] inches

or [ ][ ][ ][ ] metres

Don't know [ ]

9. What is your weight at the moment? Write number in box.

e.g. [1][4] st and [1][2] lbs

or [1][0][5][.][4][ ] kg

[ ][ ] st and [ ][ ] lbs

or [ ][ ][ ][ ][ ][ ] kg

Don't know [ ]

10. Do you currently have any health condition? Tick all that apply to you.

None ❑
Heart disease ❑
Diabetes ❑
Stroke or mini stroke ❑
Sleep apnoea ❑
High blood pressure ❑
High cholesterol ❑
Osteoarthritis ❑
Cancer ❑
Any respiratory disease e.g. asthma, COPD or sleep apnoea ❑
Prefer not to answer ❑
Other – please specify ❑

.....

Thank you for your participation

Please return your completed questionnaire in the reply paid envelope provided (no stamp needed).

Appendix 16 Validity evaluation form

Your views of Weight Loss Programme Questionnaire

We would like you provide some of your opinion or feedback from the questionnaire. Please read each statement and decide ✓ whether you answer yes, no or not sure.

Comprehension from Weight Loss Programme Questionnaire

	Yes	No	Not sure
1. Do the questions appear to be relevant?			
2. Do the questions appear to be reasonable?			
3. Do the questions appear to be unambiguous?			
4. Do the questions appear to be clear?			
5. Do the questions have a good layout?			
6. Does it appear to be a sequence of questions?			
7. Is its content comprehensive?			

8. Other opinion or feedback please specify

Thank you very much for your information